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**Ocena skuteczności intubacji dotchawiczej z wykorzystaniem
laryngoskopu Vie Scope® w warunkach symulowanego
ratunkowego zabezpieczenia dróg oddechowych**

**Rozprawa na stopień doktora nauk medycznych i nauk o zdrowiu
w dyscyplinie nauki medyczne**

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Obrona rozprawy doktorskiej przed Radą Dyscypliny Nauk Medycznych
Warszawskiego Uniwersytetu Medycznego

Warszawa 2020

Słowa kluczowe: zabezpieczenie dróg oddechowych; intubacja dotchawicza; laryngoskop; Vie Scope; medycyna ratunkowa; symulacja medyczna

Keywords: airway management; endotracheal intubation; laryngoscope; Vie Scope; emergency medicine; medical simulation

*Szczególne wyrazy wdzięczności składam mojemu promotorowi
Panu dr hab. n. med. Łukaszowi Szarpakowi za nieustającą wiarę w moją osobę,
wsparcie, cenne rozmowy oraz merytoryczną wiedzę.*

*Pracę dedykuję moim Rodzicom za nieustającą pomoc w realizowaniu moich celów
oraz nigdy niegasnącą wiarę we mnie.*

Wykaz publikacji stanowiących pracę doktorską:

- I. **Maslanka M**, Smereka J, Pruc M, Robak O, Attila K, Szarpak L, Ruetzler K. A systematic review and meta-analysis of randomized controlled trials Airtraq® versus Macintosh laryngoscope for airway management during general anesthesia: A systematic review and meta-analysis of randomized controlled trials. Disaster Emerg Med J 2020; 5(4). Accepted for publish.

(Punktacja MNiSW: 20)

- II. **Maslanka M**, Smereka J, Czyzewski L, Ladny J, Dabrowski M, Szarpak L. Vie Scope® laryngoscope versus Macintosh laryngoscope during difficult intubation performed by paramedics: A randomized cross-over manikin trial. Disaster Emerg Med J 2020; 5(3):134-141. DOI: 10.5603/DEMJ.a2020.0031.

(Punktacja MNiSW: 20)

- III. **Maslanka M**, Szarpak L, Ahuja S, Ruetzler K, Smereka J. Novel airway device Vie Scope in several pediatric airway scenario. A randomized simulation trial. Medicine (Baltimore). 2020; 99(28): e21084. doi: 10.1097/MD.00000000000021084.

(Punktacja MNiSW: 70; Impact Factor:1,552)

- IV. **Maslanka M**, Smereka J, Czyzewski L, Ladny JR, Dabrowski M, Szarpak L. Vie scope® laryngoscope versus Macintosh laryngoscope with personal protective equipment during intubation of COVID-19 resuscitation patient. Am J Emerg Med. 2020; S0735-6757(20)30779-8. doi: 10.1016/j.ajem.2020.08.085.

(Punktacja MNiSW: 70; Impact Factor: 1,911)

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WYKAZ STOSOWANYCH SKRÓTÓW

CI	Przedział ufności (<i>ang. Confidence interval</i>)
IQR	Roztęp ćwiartkowy (<i>ang. Interquartile range</i>)
MD	Średnia różnica (<i>ang. Mean difference</i>)
OR	Iloraz szans (<i>ang. Odds ratio</i>)

STRESZCZENIE W JĘZYKU POLSKIM

WSTĘP

Zespoły ratownictwa medycznego często interweniują do pacjentów, którzy z uwagi na zatrzymanie krążenia bądź stan nieprzytomności wymagają przyrządowego zabezpieczenia drożności dróg oddechowych. Intubacja dotchawicza stanowi złoty standard zabezpieczenia dróg oddechowych zarówno w warunkach przedszpitalnych jak i szpitalnych. Jest ona z uwagi na powszechną dostępność najczęściej wykonywana za pomocą standardowych laryngoskopów z łopatkami Macintosha bądź Millera. Jednakże intubacja ze wskazań ratunkowych wykonywana w warunkach medycyny ratunkowej różni się znacząco od intubacji wykonywanej w warunkach bloku operacyjnego. Presja czasu, złe warunki atmosferyczne czy też trudne drogi oddechowe mogą wpływać na zmniejszenie efektywności tej procedury. Jak wskazuje wielu autorów, skuteczność pierwszej próby intubacji z wykorzystaniem laryngoskopu z łopatką Macintosha wynosi od 57,6% do 89,94%. Stąd też poszukiwanie alternatywnych metod intubacji stanowi kluczowy element prowadzonych na świecie badań w zakresie przyrządowego zabezpieczenia drożności dróg oddechowych.

CEL PRACY

Wspólnym celem serii badań wchodzących w skład monotematycznego cyklu publikacji była ocena efektywności różnych technik intubacji dotchawiczej ze szczególnym uwzględnieniem nowego laryngoskopu Vie Scope® w warunkach symulowanej ratunkowej intubacji dotchawiczej.

MATERIAŁ I METODY

Przedstawiona rozprawa doktorska składa się z cyklu czterech badań. Trzy spośród tych badań dotyczą porównania nowego laryngoskopu Vie Scope® ze standardowym laryngoskopem z łopatką Macintosha w różnych warunkach intubacyjnych. Czwarta praca to meta-analiza stanowiąca porównanie intubacji z wykorzystaniem kanałowego laryngoskopu AirTraq z laryngoskopem Macintosha. Spośród badań wchodzących w skład monotematycznego cyklu publikacji, trzy prace to prace pełnotekstowe, zaś jedna to list do

redakcji o charakterze badawczym opublikowany w czasopiśmie The American Journal of Emergency Medicine.

Pierwsze badanie zaprojektowane jako przegląd systematyczny i meta-analiza odnosiło się do porównania efektywności intubacji z wykorzystaniem laryngoskopu AirTraQ oraz laryngoskopu z łożatką Macintosha. Stanowi ono swoisty wstęp do poruszanego w dysertacji tematu intubacji dotchawiczej z wykorzystaniem Vie Scope®. Z uwagi na brak badań dotyczących tego typu laryngoskopu, postanowiono przeprowadzić analizę efektywności laryngoskopu AirTraQ, który jest najczęściej stosowanym laryngoskopem kanałowym na świecie.

Celem drugiej pracy było porównanie efektywności intubacji dotchawiczej laryngoskopem Vie Scope®. Jako złoty standard intubacji zastosowano laryngoskop z łożatką Macintosha. W pracy udział wzięło 42 ratowników medycznych którzy mieli za zadanie wykonanie intubacji dotchawiczej w dwóch scenariuszach badawczych: a) scenariusz obrzęku języka; b) scenariusz ręczna stabilizacja odcinka szyjnego kręgosłupa.

Celem trzeciej pracy była ocena skuteczności intubacji pacjenta pediatrycznego z wykorzystaniem laryngoskopu Vie Scope®. W badaniu udział wzięło 42 ratowników medycznych, którzy posiadali minimum dwa lata doświadczenia w warunkach zespołów wyjazdowych ratownictwa medycznego. Uczestnicy badania mieli za zadanie wykonanie intubacji w sposób randomizowany krzyżowy w trzech następujących scenariuszach badawczych: a) normalne drogi oddechowe; b) obrzęk języka; c) ciągła kompresja klatki piersiowej podczas symulowanej resuscytacji krążeniowo – oddechowej.

W badaniu czwartym, którego celem było porównanie intubacji z wykorzystaniem laryngoskopu Vie Scope® i laryngoskopu z łożatką Macintosha udział wzięło również 42 ratowników medycznych. Badanie to było badaniem pionierskim w zakresie wykorzystania laryngoskopu Vie Scope® w warunkach intubacji pacjenta z podejrzeniem choroby zakaźnej. Podczas badania personel medyczny był ubrany w kombinezony ochrony osobistej chroniące przeciwko aerozolom zakaźnym.

WYNIKI

W badaniu pierwszym uwzględniono 17 badań. Skuteczność pierwszej próby intubacji z wykorzystaniem laryngoskopu kanałowego AirTraQ wynosiła 85,6%, zaś laryngoskopu

z łopatką Macintosha – 68,4%. Intubacja z wykorzystaniem AirTraq wiązała się również z krótszym czasem intubacji (MD= -3.19; 95%CI: 9.33, 2.95; P=0.31).

W badaniu drugim w scenariuszu obrzęku języka u osoby dorosłej czas wykonania intubacji z wykorzystaniem laryngoskopii bezpośredniej wynosił 55s (IQR; 46-109) i był statystycznie dłuższy niż w przypadku Vie Scope® - 30,5s (IQR; 26-35; P < 0,001) przy skuteczności pierwszej próby intubacji wynoszącej odpowiednio 95,2% i 64,3% (P <0,001). W przypadku scenariusza z manualną stabilizacją odcinka szyjnego intubacja z wykorzystaniem Vie Scope® w porównaniu z laryngoskopem Macintosha była istotnie statystycznie efektywniejsza (P < 0,001) zarówno w aspekcie czasu trwania procedury, jak i skuteczności pierwszej próby intubacji.

Badanie trzecie analizujące efektywność intubacji wykonywanej za pomocą laryngoskopu Vie Scope® wykazało całkowitą skuteczność tej metody intubacji na poziomie 100% niezależnie od scenariusza badawczego. Skuteczność pierwszej próby wynosiła 100% w przypadku normalnych dróg oddechowych, 98% w przypadku obrzęku języka oraz 91% w przypadku prowadzenia kompresji klatki piersiowej. Czas intubacji dla poszczególnych scenariuszy wynosił odpowiednio: 27s (IQR; 24–34), 27s (IQR; 25–37) oraz 29s (IQR; 25–40).

W badaniu czwartym podczas intubacji w kombinezonie ochrony osobistej wykazano statystycznie istotną redukcję czasu trwania pierwszej próby intubacji w przypadku zastosowania laryngoskopu Vie Scope® w porównaniu z laryngoskopem z łopatką Macintosha (odpowiednio, 28,5s i 44s; P < 0,001). Skuteczność pierwszej próby intubacji z wykorzystaniem badanych urządzeń była zróżnicowana i wynosiła odpowiednio 92,9% i 50,0%, zaś całkowita skuteczność intubacji wynosiła 100% i 90,5% (odpowiednio dla Vie Scope® i laryngoskopu Macintosha).

WNIOSKI

Przeprowadzone badania pozwalają na sformułowanie następujących wniosków:

- AirTraq jako przykład laryngoskopu kanałowego stanowi alternatywę dla laryngoskopii bezpośredniej zwiększając skuteczność pierwszej próby intubacji, zwłaszcza w aspekcie unieruchomienia odcinka szyjnego kręgosłupa.

- Intubacja dotchawicza z wykorzystaniem Vie Scope® w porównaniu z laryngoskopem z łopatką Macintosha jest wykazuje wyższą efektywność w przypadku zabezpieczania dróg oddechowych pacjenta pediatrycznego.
- Vie Scope® w badaniu symulacyjnym wykazuje wysoką skuteczność pierwszej próby intubacji zarówno w aspekcie normalnych jak i trudnych dróg oddechowych.
- W przypadku intubacji pacjenta z podejrzeniem choroby zakaźnej, gdy personel medyczny ubrany jest w kombinezony ochronne zastosowanie laryngoskopu Vie Scope® znacząco skraca czas intubacji jak również zwiększa szanse na skuteczną intubację.

STRESZCZENIE W JĘZYKU ANGIELSKIM

ASSESSMENT OF THE EFFECTIVENESS OF ENDOTRACHEAL INTUBATION WITH THE USE OF A VIE SCOPE® LARYNGOSCOPE IN THE CONDITIONS OF SIMULATED EMERGENCY AIRWAY MANAGEMENT

INTRODUCTION

Emergency medical teams often intervene in patients who, because of cardiac arrest or unconsciousness, require respiratory device protection. Tracheal intubation is the gold standard of airway protection in both pre-hospital and inpatient settings. Due to the widespread availability, it is most often performed with standard Macintosh or Miller laryngoscopes. However, emergency intubation performed in an emergency medicine setting differ significantly from intubation performed in an operating theater setting. Time pressure, severe weather, or difficult airways may reduce the effectiveness of this procedure. As showed by many authors, the effectiveness of the first intubation attempt with the use of a Macintosh laryngoscope is from 57.6% to 89.94%. Hence, the search for alternative methods of intubation is a key element of research conducted in the world in device protection of airway patency.

Purpose

The common goal of the series of studies included in the monothematic publication cycle was to evaluate the effectiveness of various techniques for endotracheal intubation, with particular emphasis on the new Vie Scope® laryngoscope under simulated rescue endotracheal intubation.

MATERIAL AND METHODS

The presented doctoral dissertation comprises a series of four studies. Three studies compare the new Vie Scope® Laryngoscope with a standard Macintosh Blade Laryngoscope under different intubation conditions. The fourth paper is a meta-analysis comparing intubation using the AirTraq canal laryngoscope with the Macintosh laryngoscope. Of the

studies included in the monothematic publication cycle, three are full-text papers and one is a research letter to the editor published in The American Journal of Emergency Medicine. The first study, designed as a systematic review and meta-analysis, compared the effectiveness of intubation with the AirTraQ laryngoscope and the Macintosh blade laryngoscope. It is a kind of introduction to endotracheal intubation with the use of Vie Scope® discussed in the dissertation. Because of the lack of research on this type of laryngoscope, I decided it to analyze the effectiveness of the AirTraQ laryngoscope, which is the most widely used canal laryngoscope in the world.

The aim of the second study was to compare the effectiveness of endotracheal intubation with the Vie Scope® laryngoscope. A Macintosh laryngoscope was used as the gold standard of intubation. 42 paramedics taken part in the study, tasked with performing endotracheal intubation in two research scenarios: a) tongue edema scenario; b) manual stabilization of the cervical spine scenario.

The aim of the third study was to evaluate the effectiveness of intubation of a pediatric patient with the use of the Vie Scope® laryngoscope. The study involved 42 paramedics who had at least two years of experience in the conditions of medical rescue teams. The study participants were asked to perform a randomized cross intubation in the following three research scenarios: a) normal airway; b) tongue edema; c) continuous chest compression.

42 paramedics also took part in the fourth study, which aimed to compare intubation with the Vie Scope® laryngoscope and the Macintosh laryngoscope. This study was a pioneering study in using the Vie Scope® laryngoscope in intubation conditions of a patient suspected of having an infectious disease. During the study, medical personnel wore personal protective coveralls to protect against infectious aerosols.

RESULTS

The first study included 17 studies. The effectiveness of the first intubation attempt using the AirTraQ canal laryngoscope was 85.6%, and the Macintosh laryngoscope with 68.4%. AirTraQ intubation was also associated with a shorter intubation time (MD = -3.19; 95% CI: 9.33, 2.95; P = 0.31).

In the second study in the adult tongue edema scenario, the duration of intubation using direct laryngoscopy was 55s (IQR; 46-109) and was statistically longer than with Vie

Scope® - 30.5s (IQR; 26-35; $P < 0.001$)) with the effectiveness of the first intubation attempt of 95.2% and 64.3%, respectively ($P < 0.001$). In the scenario with manual cervical stabilization, intubation using the Vie Scope® compared to the Macintosh laryngoscope was statistically significantly more effective ($P < 0.001$) both in terms of the duration of the procedure and the effectiveness of the first intubation attempt.

The third study analyzing the effectiveness of intubation performed with the Vie Scope® laryngoscope showed the total effectiveness of this method of intubation at the level of 100% regardless of the research scenario. The effectiveness of the first attempt was 100% for normal airways, 98% for tongue swelling, and 91% for chest compression. The intubation time for individual scenarios was respectively: 27s (IQR; 24–34), 27s (IQR; 25–37) and 29s (IQR; 25–40).

In the fourth study, during intubation in a PPE, a statistically significant reduction in the duration of the first intubation attempt was demonstrated with the Vie Scope® laryngoscope compared to the Macintosh laryngoscope (28.5s and 44s, respectively; $P < 0.001$). The effectiveness of the first intubation attempt with the devices tested was varied and amounted to 92.9% and 50.0%, respectively, and the total intubation efficiency was 100% and 90.5% (for Vie Scope® and Macintosh laryngoscope, respectively).

CONCLUSIONS

The conducted research allows for the following conclusions:

- AirTraq as an example of a canal laryngoscope is an alternative to direct laryngoscopy, increasing the effectiveness of the first intubation attempt, especially in terms of immobilization of the cervical spine.
- Tracheal intubation with the Vie Scope® is more effective than a Macintosh laryngoscope in securing the airway of a pediatric patient.
- Vie Scope® in the simulation test shows high effectiveness of the first intubation attempt, both in terms of normal and difficult airways.
- In the case of intubation of a patient suspected of having an infectious disease and medical personnel wearing protective suits, the use of the Vie Scope® laryngoscope significantly reduces intubation time and increases the chances of successful intubation.

1. WSTĘP

1.1. Miejsce zabezpieczenia dróg oddechowych w medycynie ratunkowej

Zabezpieczenie drożności dróg oddechowych powinno stanowić jedną z podstawowych umiejętności jakimi winien wykazywać się personel zespołów systemu Państwowego Ratownictwa Medycznego [1,2]. To właśnie lekarze, ratownicy medyczni i pielęgniarki pracujące w ramach zespołów ratownictwa relatywnie często spotykają się z koniecznością przyrządowego zabezpieczenia drożności dróg oddechowych.

Obecnie na rynku medyczny dostępnych jest wiele urządzeń do zabezpieczania drożności dróg oddechowych, począwszy od rurek ustno- i nosowo-gardłowych, poprzez maski krtaniowe, rurki krtaniowe, rurki typu Combitube® aż na rurkach intubacyjnych bądź zestawach do konikopunkcji kończąc [3]. Jednakże to intubacja dotchawicza stanowi po dziś dzień „złoty standard” zabezpieczenia drożności dróg oddechowych w warunkach medycyny ratunkowej [4].

Intubacja dotchawicza jako procedura specjalistyczna wymaga od operatora dużych umiejętności w zakresie zabezpieczania dróg oddechowych i powinna być wykonywana przez najbardziej doświadczoną osobę w zespole. W nieumiejętnych rękach może być obarczona dużym ryzykiem powikłań, począwszy od uszkodzenia zębów, poprzez uszkodzenie tkanek i wywołanie krwawienia, złamanie nagłośni, uszkodzenie fałdów głosowych czy też rozerwanie tchawicy i wywołanie zagrażającej życiu odmy śródpiersia.

Zabezpieczenie przyrządowe dróg oddechowych za pomocą rurki intubacyjnej pozwala na odizolowanie dróg oddechowych. Dzięki temu możliwe jest stosowanie wentylacji z dodatnim ciśnieniem końcowo wydechowym jak również prowadzenie asynchronicznej resuscytacji bez obawy na regurgitację i aspirację treści pokarmowej do dróg oddechowych. Izolacja dróg oddechowych w dobie pandemii COVID-19 nabiera szczególnego znaczenia. Szybkie zabezpieczenie dróg oddechowych u pacjentów zakaźnych nieprzytomnych wymagających udrożnienia dróg oddechowych może zredukować ryzyko kontaminacji otoczenia i samych ratowników zakaźnym aerozolem oddechowym pacjenta.

1.2. Wybrane metody intubacji dotchawiczej

1.2.1. Laryngoscopia bezpośrednia

Laryngoscopia bezpośrednia to metoda intubacji oparta na bezpośrednim wzrokowym obserwowaniu wejścia do głośni podczas wykonywania intubacji dotchawiczej [5]. Laryngoscopia bezpośrednia oparta jest w głównej mierze na wykorzystaniu laryngoskopów z łopatkami Millera bądź Macintosha. Łopatki te różnią się kształtem oraz samym sposobem intubacji dotchawiczej (Rycina 1).



Rycina 1.. Łopatką Macintosha (zakrzywiona) oraz Millera (prosta).

Źródło: Archiwum autora.

Z uwagi na powszechną dostępność laryngoskopów z łopatkami Macintosha oraz Miller metoda ta uznawana jest za złoty standard intubacji dotchawiczej. Wartym podkreślenia jest fakt, iż skuteczność intubacji w warunkach przedszpitalnych bądź wczesno szpitalnych, jak ma to miejsce w ramach zespołów wyjazdowych ratownictwa medycznego bądź na Szpitalnych Oddziałach Ratunkowych opartej o laryngoskopię bezpośrednią jest obarczona dużym ryzykiem niepowodzenia. Jak wskazuje wielu autorów, skuteczność pierwszej próby intubacji z wykorzystaniem laryngoskopu z łopatką Macintosha wynosi od 57,6% do 89,94%

[6,7,8]. Powyższy problem nie dotyczy tylko dorosłych, ale odnosi się również do pacjentów pediatrycznych [9,10]. Jak wskazuje Crewdson w swojej meta-analizie spośród 19178 pacjentów wymagających intubacji dotchawiczej, tylko 14913 przypadków zakończyło się sukcesem podczas pierwszej próby intubacji, co stanowiło skuteczność na poziomie 77,8% [11]. Rognås i wsp. wskazywali skuteczność pierwszej próby intubacji na poziomie 85,8% przypadków, jednakże wskazali również na 22% ryzyko komplikacji, w tym hipotensja stanowiła 7,3%, zaś hipoksja – 5,3% przypadków [12].

1.2.2. Laryngoskopy kanałowe

AirTraq (Prodol Meditec, Vizcaya, Spain) to sztandarowy laryngoskop z rodzaju laryngoskopów kanałowych. Airtraq SP dostępne są w różnych rozmiarach dla wszystkich grup wiekowych. Laryngoskop wyposażony jest w źródło światła typu LED oraz system "anti fog" ułatwiający dobrą widoczność w niesprzyjających warunkach. Zintegrowany kanał na rurkę intubacyjną znacznie upraszcza i przyspiesza procedurę intubacji, dzięki utrzymywaniu rurki intubacyjnej w osi widoczności laryngoskopu (Rycina 2).

Laryngoskop Airtraq znajduje zastosowanie w warunkach przedszpitalnych oraz blokach operacyjnych. Dodatkowe akcesoria jak kamera WiFi i uniwersalny adapter do smartfonów pozwalają przekształcić zwykły optyczny laryngoskop Airtraq w wideolaryngoskop. Hoshijima i wsp. w swojej meta-analizie obejmującej 11 badań wykazali, iż intubacja za pomocą AirTraq w porównaniu z laryngoskopią bezpośrednią redukuje odpowiedź hemodynamiczną na intubację dotchawiczą [13]. Z kolei meta-analiza przeprowadzona przez Lu i wsp. wskazuje na przewagę AirTraq nad laryngoskopem z łopatką Macintosha, zwłaszcza w aspekcie nowych użytkowników [14]. Nasim i wsp. w badaniu symulacyjnym wskazują, iż ratownicy medyczni byli z wyższą efektywnością w stanie wykonać intubację pacjenta z trudnymi drogami oddechowymi [15]. Trimmel i wsp. jednakże nie zalecają stosowania AirTraq w warunkach przedszpitalnych, bez uprzedniego nabycia odpowiednich umiejętności w warunkach bloku operacyjnego [16].

Vie Scope® (Adroid Surgical Ltd., Oklahoma, OK, USA) jest jednym z najnowszych laryngoskopów dostępnych na rynku medycznym. Jest urządzeniem jednorazowy. Jest to laryngoskop zbudowany z rękojeści wyposażonej w źródło światła, do którego przytwierdzona jest cylindryczna rurka wykonana z plexi i przewodząca światło (Rycina 3).



Rycina 2. Laryngoskop AirTraq.

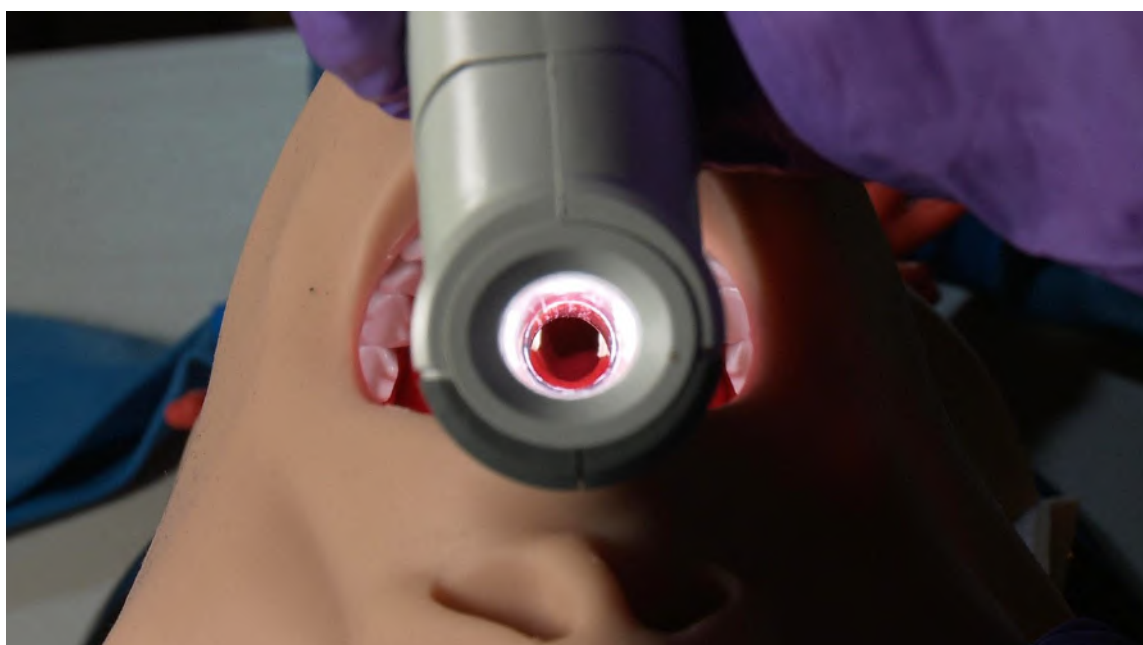
Źródło: archiwum autora.



Rycina 3. Intubacja z wykorzystaniem laryngoskopu Vie Scope®.

Źródło: archiwum autora.

Obraz obserwowany jest za pomocą wizjera (Rycina 4). Intubacja dotchawicza z wykorzystaniem Vie Scope oparta jest na kilku krokach: 1) należy prowadzić urządzenie do jamy ustnej pacjenta i uwidocznienie wejście do głośni; 2) poprzez wnętrze cylindra należy wprowadzić prowadnicę Bougie na odpowiednią głębokość; 3) trzymając prowadnicę Bougie należy usunąć laryngoskop; 4) po prowadnicy należy zsunąć rurkę intubacyjną; 5) należy usunąć prowadnicę, napętnić mankiet uszczelniający rurki intubacyjnej oraz potwierdzić poprawność intubacji dotchawiczej.



Rycina 4. Uwidocznienie głośni za pomocą laryngoskopu Vie Scope®.

Źródło: archiwum autora.

Z uwagi na fakt, iż jest to nowe urządzenie na rynku medycznym dostępność badań wskazujących na efektywność intubacji z wykorzystaniem Vie Scope jest ograniczona i sprowadza się tylko i wyłącznie do badań stanowiących cykl niniejszej rozprawy doktorskiej. Jednakże jak udowodniono, Vie Scope może znaleźć zastosowanie zarówno podczas intubacji dzieci jak i dorosłych, tak w warunkach normalnych dróg oddechowych jak i sytuacji, gdy wykonujemy intubację pacjenta z unieruchomieniem odcinka szyjnego kręgosłupa czy też podczas resuscytacji. Intubacja za pomocą Vie Scope jak udowodniono w badaniach własnych jest również możliwa przy korzystaniu przez personel medyczny z pełnych kombinezonów ochronnych zabezpieczających przed infekcją wirusową od pacjentów z COVID-19 (Rycina 5).



Rycina 5. Intubacja z wykorzystaniem Vie Scope® w warunkach stosowania kombinezonu ochrony osobistej. Źródło: archiwum autora.

1.2.3. Wideo-laryngoskopy z łopatkami typu Macintosh

Rozwój techniki medycznej pozwolił na wprowadzenie na rynek medyczny wielu typów laryngoskopów, począwszy od laryngoskopów, gdzie rękojeść z łopatką połączone są z monitorem za pomocą dedykowanego przewodu (np. GlideScope) po kompaktowe laryngoskopy do których rękojeści na stałe dołączony jest mały monitor (np. McGrath, Intubrite).

Laryngoskop GlideScope (Verathon Inc., Bothell, WA, USA) w wersji GVL jest wideolaryngoskopem, który jest zbudowany z rękojeści z łopatką scalonych w jeden element, na którego dystalnej części umiejscowiona jest kamera. Obraz z kamery przekazywany jest za pomocą dedykowanego przewodu do monitora (Rycina 6). Meta-analiza opracowana przez Griesdale i wsp. obejmująca 17 badań i 1998 pacjentów wskazuje na przewagę GlideScope względem laryngoskopii bezpośredniej w zakresie stopnia uwidocznienia głośni [17]. Russell i wsp. wskazują, iż GlideScope w porównaniu z laryngoskopem z łopatką Macintosha pozwala na lepsze uwidacznianie głośni w przypadku

pacjentów z trudnymi drogami oddechowymi [18]. Jednakże jak wskazują Trimmel i wsp. należy zwrócić szczególną uwagę na ryzyko powikłań, której jest istotnie wyższe w przypadku GlideScope niż laryngoskopu z łopatką Macintosha [19].



Rycina 6. Wideolaryngoskop GlideScope.

Źródło: archiwum autora.

Laryngoskop McGrath (Medtronic Inc., Minneapolis, MN, USA) jest przykładem wideolaryngoskopu. Urządzenie jest zbudowane z rękojeści, do której na stałe przytwierdzona jest prowadnica zakończona kamerą. Do laryngoskopu dedykowane są jednorazowe nasadki na prowadnicę, które kształtem są zbliżone do łopatek typu Macintosh (Rycina 7).

Obraz jest przekazywany bezpośrednio na monitor przytwierdzony do rękojeści. Badanie Kreutzigera i wsp. przeprowadzone w Lotniczym Pogotowiu Ratunkowym w Austrii wykazała skuteczność intubacji z zastosowaniem McGrath na poziomie 98,1% [20]. Choi i wsp. prowadząc natomiast badanie symulacyjne z unieruchomieniem odcinka szyjnego wskazuje również na przewagę laryngoskopu McGrath nad laryngoskopią bezpośrednią w zakresie intubacji tego typu pacjentów [21].



Rycina 7. Wideolaryngoskop McGrath MAC.

Źródło: archiwum autora.

Przewaga laryngoskopu McGrath polegała na lepszym uwidocznieniu głośni (Rycina 8), szybszym wykonaniu procedury, mniejszym nacisku na zęby oraz mniejszej liczby prób intubacji.

W przypadku większości wideolaryngoskopów – zarówno wyposażonych w łopatkę typu Macintosh jak również mających łopatkę o budowie kanałowej – liczne badania wskazują na znacznie krótszą krzywą uczenia aniżeli ma to miejsce w przypadku laryngoskopii bezpośredniej [22,23].



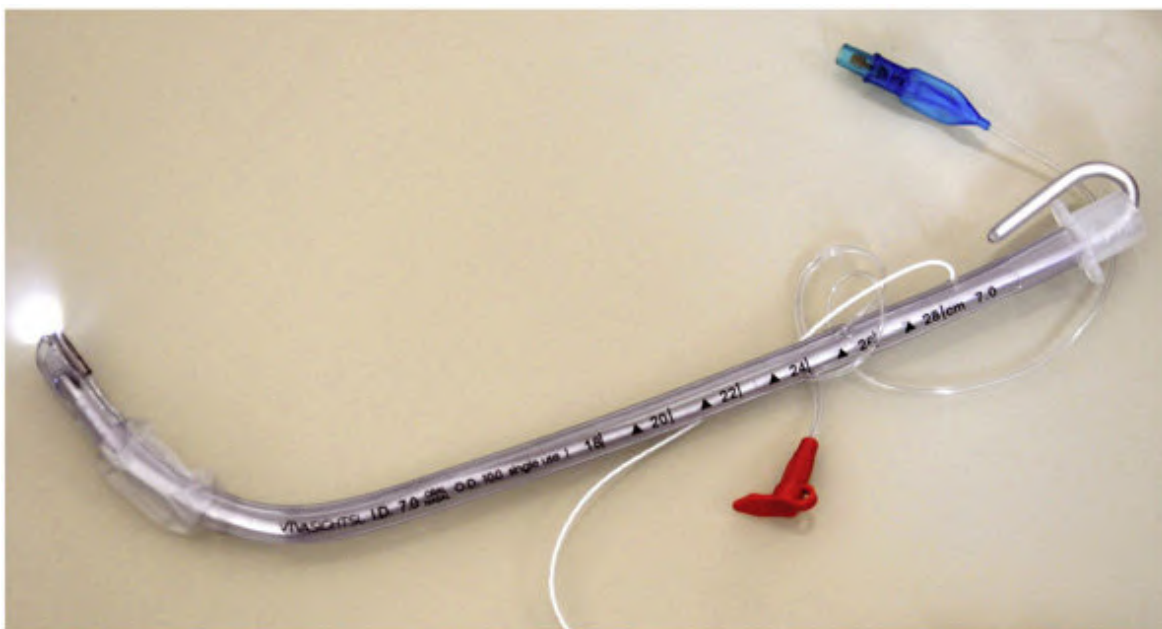
Rycina 8. Intubacja z wykorzystaniem laryngoskopu McGrath MAC.

Źródło: archiwum autora.

1.2.4. Rurki intubacyjne z torem wizyjnym

Rurki intubacyjne z torem wizyjnym to relatywnie nowe narzędzie do intubacji dotchawiczej. Przykładem takiego rozwiązania może być rurka ETVIEW (ETView; ETView Ltd. Misgav, Izrael). Występuje ona w dwóch wersjach jako rurka jednoświatłowa z oznaczeniem SL (*ang. Single lumen*) oraz w wersji dwuświatłowej – DL (*ang. Double lumen*). Rurka intubacyjna ETVIEW swoją budową przypomina standardową rurkę intubacyjną, jednakże zatopiona jest w jej strukturze kamera oraz przewód umożliwiający podłączenie kamery do dedykowanego monitora (Rycina 9).

Dzięki umieszczeniu kamery na dystalnym końcu rurki, możliwe jest podczas intubacji dotchawiczej obserwowanie w czasie rzeczywistym obrazu z końca dystalnego rurki intubacyjnej, dzięki czemu operator delikatnie manewrując rurką jest w stanie wprowadzić ją do tchawicy nawet w przypadku trudnych dróg oddechowych. Kamera dodatkowo wyposażona jest w źródło światła oświetlające struktury anatomiczne (Rycina 10).



Rycina 9. Rurka intubacyjna z torem wizyjnym ETView SL.

Źródło: archiwum autora.



Rycina 10. Uwidocznienie głośni za pomocą rurki ETView.

Źródło: archiwum autora.

Jednym z głównych problemów wszystkich urządzeń przekazujących obraz podczas intubacji (wideolaryngoskopy, rurki z torem wizyjnym) jest możliwość zabrudzenia soczewki kamery płynami fizjologicznymi, w tym krwią. W przypadku urządzenia ETView

został ten problem rozwiązany poprzez umiejscowienie po obu stronach kamery zakończeń przewodów, za pomocą których możliwe jest przepłukanie soczewki solą fizjologiczną bądź innym płynem. Znajdują one główne zastosowanie w warunkach bloku operacyjnego oraz oddziałów intensywnej terapii. Dzięki wersji dwu-światłowej chętnie stosowane są przez anestezjologów podczas operacji kardiochirurgicznych bądź torakochirurgicznych (Rycina 11) [24].



Rycina 11. Rurka intubacyjna dwuświatłowa ETView DL.

Źródło: archiwum autora.

Jak wskazuje Oh i wsp. w swojej meta-analizie krzywa uczenia się intubacji z wykorzystaniem ETView jest krótka i krótkie szkolenie pozwala na uzyskiwanie zadowalających efektów w aspekcie tak skuteczności intubacji jak i czasu trwania procedury intubacji [25]. Ma to szczególne znaczenie w aspekcie mniej doświadczonych osób wykonujących intubację dotchawiczą, gdyż jak wspomniano uprzednio krzywa uczenia w przypadku laryngoskopii jest znacznie wyższa [26,27]. Jak wskazują badania naukowe ETView może znaleźć zastosowanie w wielu sytuacjach klinicznych. Gawłowski i wsp. wskazują na wysoką skuteczność intubacji z wykorzystaniem ETView w warunkach unieruchomienia odcinka szyjnego kręgosłupa [28]. Z kolei Truszczyński i wsp. wskazuje na przewagę ETView nad laryngoskopem z łopatką Macintosh w przypadku intubacji w warunkach ciągłej kompresji klatki piersiowej [29]. Przydatność ETView jako metody intubacji dotchawiczej w warunkach resuscytacji krążeniowo – oddechowej wskazują również badania Kurowskiego [30] oraz Sierżantowicz [31].

2. CEL PRACY

Wspólnym celem serii badań wchodzących w skład monotematycznego cyklu publikacji była ocena efektywności różnych technik intubacji dotchawiczej ze szczególnym uwzględnieniem nowego laryngoskopu Vie Scope® w warunkach symulowanej ratunkowej intubacji dotchawiczej.

3. KOPIE OPUBLIKOWANYCH PRAC

Airtraq® versus Macintosh laryngoscope for airway management during general anesthesia:

A systematic review and meta-analysis of randomized controlled trials

Running head: Airtraq versus Macintosh laryngoscope

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ABSTRACT

Background: Despite the introduction of supraglottic devices for ventilation, endotracheal intubation is still a gold standard for airway management in both prehospital and operating theatre conditions. This systematic review and meta-analysis were conducted to investigate the effectiveness and safety of Airtraq vs. Macintosh laryngoscope for endotracheal intubation during general anesthesia.

Methods:

The current issue of Pubmed, Embase, Cochrane, Web of science, Scopus (from database inception to October 20, 2020) was searched. Randomized controlled trials (RCT) comparing Airtraq and Macintosh laryngoscope were included in this meta-analysis. The primary outcomes were the success rate of first attempt intubation and intubation time. Secondary outcomes were overall intubation success rate, malposition, and adverse events. Review Manager 5.4 software was used to perform the pooled analysis and assess the risk of bias for each eligible RCT.

Results:

Seventeen studies were included in the review for data extraction. First attempt success rate was 85.6% for ATQ vs. 68.4% for MAC (OR=3.00; 95%CI: 1.37, 6.60; P=0.006; $I^2 = 63\%$). The use of ATQ and MAC for intubation in cervical spine immobilization was associated with the effectiveness of the first intubation attempt at 98.6% vs. 71.1% (OR=16.40; 95%CI: 3.55, 78.87; P<0.001; $I^2=0\%$). Intubation time with ATQ was shorter than with MAC (MD= -3.19; 95%CI: -9.33, 2.95; P=0.31; $I^2=97\%$). The endotracheal intubation during cervical spinal intubation was

associated with significantly shorter procedure duration for ATQ than for MAC (MD=-10.30; 95%CI: -18.43, -2.18; P=0.01; I²=74%). The total efficacy of intubation, which for ATQ and MAC varied and was 86.7% vs. 80.6% respectively (OR=2.88; 95%CI: 1.61, 5.13; P<0.001; I²=0%).

Conclusions:

Based on the results of this analysis, we conclude that ATQ can reduce the failed first intubation attempt, especially in cervical manual inline stabilization patients, and reduces the time needed to obtain airway management, but does not provide significant benefits on other adverse events associated with tracheal intubation. Further studies are needed to demonstrate whether severe adverse events are significantly different between the two devices.

Keywords:

Airway management; endotracheal intubation; laryngoscope; systematic review; meta-analysis.

1. BACKGROUND

Various surgical procedures are performed under local and regional anesthesia. Much of the surgical procedures can be performed using supraglottic devices, but still, in many surgical procedures, general anesthesia is performed with airway protection by endotracheal intubation [1].

Providing adequate patient ventilation, airway management and especially endotracheal intubation are the basic procedures performed by an anesthesiologist [2]. Unfortunately, in some cases, endotracheal intubation is more or less difficult and in some cases may not be possible [3,4]. There are several scales for assessing the patient's airway and possible difficulties in endotracheal intubation. These scales facilitate the selection of the right technique, the preparation of appropriate equipment, including alternative ones, and above all, is based on the involvement of experienced medical personnel.

Improper airway management may result in a variety of complications, including the risk of death. This is particularly important in emergency and life-saving patients and airway procedures in emergency medicine. Unrecognized esophageal intubation may have catastrophic consequences for the patient [3]. The problem of difficult airways is particularly important in patients with the severe clinical course of COVID-19, where hypoxia progresses very quickly and difficulties in securing the airway may pose a real threat to the patient's life, especially in case of limitations for medical personnel related to the use of personal protective equipment and lack of instant assistance from more experienced medical personnel [5].

Various parameters can be used to assess the efficacy of airway management especially endotracheal intubation, including the total duration of the procedure, the percentage of successful intubations at the first attempt, the total number of intubation

attempts, and the complications of endotracheal intubation for both normal and difficult airways, including cervical spine immobilization.

This systematic review and meta-analysis was conducted to investigate the effectiveness and safety of Airtraq vs. Macintosh laryngoscope for endotracheal intubation during general anesthesia.

2. METHODS

This systematic review and meta-analysis was conducted following the recommendations of The Cochrane Handbook for Systematic Reviews of Interventions and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement [6]. Before starting the study, all authors agreed on the analysis methods and the inclusion and exclusion criteria to be applied.

2.1. Data sources and search strategy

Two authors (M.M. and L.S.) independently searched relevant literature. The current issue of Pubmed, Embase, Cochrane, Web of science, Scopus (from database inception to October 20, 2020) was searched. Study authors were mailed for any useful information. The whole search strategy used free words including "Airtraq" OR "ATQ" OR "channeled laryngoscop*" AND "Macintosh" OR "MAC" OR "direct laryngoscop*" AND "endotracheal intubation" OR "tracheal intubation" OR "intubation" OR "airway" OR "airway management" OR "ETI". The reference lists of all eligible trials and reviews were screened for additional citations. We restricted publication to the English language.

2.2. Eligibility criteria:

Randomized controlled trials comparing Airtraq and Macintosh laryngoscope and reporting the efficacy parameters of tracheal intubations were included. The pre-hospital study, conference papers, letters to the editor, cadaver study, simulated study, or case reports were excluded.

2.3. Data extraction:

Two reviewers (M.M. and J.S.) independently extracted data from each study by using a predefined data extraction form. Any disagreement unresolved by the discussion was resolved in consultation with a third reviewer (L.S.). The following variables were extracted from the studies: first author name, country, study design, airway management setting, type of operator, no. of patients, age, sex, the success of intubation attempts, intubation time, adverse events, inclusion and exclusion criteria, outcomes and findings. In case if the above variables were not found in the articles, we requested the data from their authors via email.

2.4. Risk of bias assessment

The risk of bias for each eligible study was independently assessed by two review authors (J.S. and M.M.). For randomized controlled trials the Cochrane Collaboration's tool (The Cochrane Collaboration, Oxford, UK) was used to assess the risk of bias [7]. This tool is widely used to assess the methodological quality of RCTs and consists of the following six items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective outcome reporting.

According to the previous trials [8] each bias was graded “yes”, “no”, or “unclear”, which reflected a high risk of bias, low risk of bias, and uncertain bias, respectively.

2.5. Statistical analysis

Meta-analysis was performed by RevMan 5.4EN (Cochrane Collaboration, Oxford, UK). A two-tailed $P < 0.05$ was considered statistically significant. All statistical variables were determined with 95% confidence interval (CI) to estimate the range of plausible treatment effects. In case when the continuous outcome was reported in a study as median, range, and interquartile range, we estimated means and standard deviations using the formula described by Hozo et al. [9]. We employed the inverse-variance method for the continuous outcomes and the Mantel-Haenszel models for all dichotomous outcomes. We calculated mean differences (MD) for continuous measurements and odds ratios (OR) for dichotomous outcomes.

Statistical heterogeneity across trials was estimated using the I^2 statistic [10], in which $I^2 < 30\%$ denotes “low heterogeneity,” $I^2 = 30\%$ to 50% represents “moderate heterogeneity,” and $I^2 > 50\%$ denotes “substantial heterogeneity” [11]. The random-effects model was used for $I^2 > 50\%$; otherwise, the fixed effects model was employed. The Mantel–Haenszel method was used to synthesize dichotomous data.

3. RESULTS

3.1. Characteristics of included studies

The search strategy details are provided in Figure 1. Using a search strategy, a total of 507 papers were identified. A total of 136 studies were removed due to duplicates. In the

remaining 371 studies, 329 were excluded because of patients not eligible for the study purpose, abstract unavailable, reviews, or letters.

Twenty-five articles were excluded as follows: four were not RCT designed studies, four were only published abstracts, three were letters to the editor, seven evaluated different outcomes to this study (for the transitivity assumption not to be violated), six were simulation trials, and one was a redundant publication. Finally, 17 studies were eventually included in the review for data extraction [12-28].

3.2. Risk of bias assessment for included studies

Detailed description regarding the risk of bias of the included studies is shown in Supplementary digital content (SDC) Of the 17 included studies, all were RCTs [12-28], and six of them were single-blinded [12,13,22-25,]. All studies (100%) were assessed as having a low risk of bias about Selective reporting and Other potential sources of bias.

3.3. Primary outcome

Twelve studies (n=782 patients) reported the first attempt success rate of intubation with ATQ and MAC [12,13,17,18,20,21-26,28]. In case of ATQ first attempt success rate was 85.6% vs. 68.4% for MAC (OR=3.00; 95%CI: 1.37, 6.60; P=0.006; $I^2 = 63\%$; Figure 2). The additional analysis showed that the use of ATQ and MAC in cervical spine immobilization was associated with the effectiveness of the first intubation attempt at 98.6% vs. 71.1% (OR=16.40; 95%CI: 3.55, 78.87; P<0.001; $I^2=0\%$) respectively.

The intubation time was reported in fourteen publications with ATQ was shorter than with MAC (MD= -3.19; 95%CI: -9.33, 2.95; P=0.31; $I^2=97\%$; Figure 3)[12,13,15-17,19,21-28].

The endotracheal intubation during cervical spinal intubation was associated with significantly shorter procedure duration for ATQ than for MAC (MD=-10.30; 95%CI: -18.43, -2.18; P=0.01; $I^2=74\%$). For intubation without cervical immobilization of the spine a slight superiority of ATQ over MAC in terms of intubation time was noted (MD = -82; 95%CI: -7.85, 6.20; P=0.82; $I^2=98\%$).

3.4. Secondary outcomes

Thirteen studies indicated the total effectiveness of intubation, which for ATQ and MAC varied 86.7% vs. 80.6% respectively (OR=2.88; 95%CI: 1.61, 5.13; P<0.001; $I^2=0\%$; Figure 4)[12,14,15-18,20-25,28].

One study [16] indicated that cervical spine movements were lower for ATQ intubation than for MAC (MD=-12.70; 95%CI: -14.92, -10.48; P<0.001).

Pooled analysis showed that ATQ intubation required less head positioning change during the procedure (23.0%) than MAC (32.1%; OR=0.23; 95%CI: 0.01, 5.16; P=0.35; $I^2=87\%$). The need for external laryngeal manipulation was also lower (3.3%) with ATQ than with MAC (36.6%; OR=0.07; 95%CI: 0.04, 0.13; P<0.001; $I^2=28\%$).

3.5. Adverse events

A detailed list of adverse events is presented in Table 2. The most common complication among the studies included in the meta-analysis was a sore throat and it concerned 41.7% of patients intubated with ATQ and 57.7% of those intubated with MAC. Intubation with ATQ was associated with a lower risk of blood staining of laryngoscope blade, laryngospasm, and

mucosal trauma compared to MAC. In the case of lips trauma, an inverse relationship was noted, where trauma with ATQ was more than 5.5% higher than with MAC.

4. DISCUSSION

In this review, we showed that Airtraq was the most useful device in terms of the success rate of the first attempt at endotracheal intubation under general anesthesia conditions. In the meta-analysis, the efficacy of the first intubation attempt with Airtraq was higher than with direct laryngoscopy. This relationship was even more evident when intubated under manual in-line neck stabilization. Many articles indicate the advantage of video laryngoscopy over direct laryngoscopy when intubating patients with "difficult" airways (i.e. tongue edema) or when there are limitations in the patient's position due to the use of cervical collars [29,30], manual in-line stabilization [31,32] or continuous chest compression during cardiopulmonary resuscitation [33,34]. It is therefore advisable to use alternative intubation methods to Macintosh laryngoscope in such cases, which will increase the effectiveness of intubation as well as may shorten the time of the procedure. An additional problem observed with multiple endotracheal intubation attempts is the vicious circle phenomenon in which each subsequent intubation attempt increases soft tissue trauma - bleeding and swelling, leading ultimately to a situation described by the Difficult Airway Society (DAS) as "can't intubate, can't ventilate" [35]. Then the only solution is cricothyrotomy or tracheostomy [36].

Rapid airway management including endotracheal intubation in both prehospital and operating theatre conditions is essential. The prolonged endotracheal intubation procedure may cause hypoxia and related damage to vital organs due to hypoxia. As Wozniak et al. indicate, intubation attempts should be limited to a maximum of 30 seconds. Prolonging the

intubation more than 30 seconds leads to greater hypoxia and may contribute to increased neonatal morbidity, with no effect on success rate [37].

4.1. Limitations

There are some limitations in our analysis that deserve special attention. The first limitation is the fact that only randomized controlled trials are included in the study, but this type of study guarantees the highest quality of results. The second limitation is the inclusion of articles comparing only Airtraq vs. Macintosh laryngoscope. However, this was deliberate. In the further parts of the series of studies, the authors plan to conduct meta-analyses concerning other types of laryngoscopes.

5. CONCLUSIONS

This systematic review and meta-analysis revealed that ATQ can reduce the failed first intubation attempt, especially in cervical manual inline stabilization patients, and reduces the time needed to obtain airway management, but does not provide significant benefits on other adverse events associated with tracheal intubation. Further studies are needed to demonstrate whether severe adverse events are significantly different between the two devices.

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Table 1. Characteristics of included studies.

Table 2. Adverse events reported in the included studies.

Figure 1. Flow diagram showing stages of database searching and study selection.

Figure 2. Forest plot of first intubation attempt success rate in Airtraq vs. Macintosh groups. The center of each square represents the odds ratio for individual trials, and the corresponding horizontal line stands for a 95% confidence interval. The diamonds represent pooled results.

Figure 3. Forest plot of intubation time rate in Airtraq vs. Macintosh groups. The center of each square represents the mean difference for individual trials, and the corresponding horizontal line stands for a 95% confidence interval. The diamonds represent pooled results.

Figure 4. Forest plot of the overall intubation success rate in Airtraq vs. Macintosh groups. The center of each square represents the odds ratio for individual trials, and the corresponding horizontal line stands for a 95% confidence interval. The diamonds represent pooled results.

Authors contributions

The authors' primary responsibilities were as follows: M.M. and L.S. developed the research question. M.M. and L.S., designed the study. M.M., J.S. and L.S. collected the data. M.M., J.S., and K.R.. analyzed the data and interpreted the results. M.M. and L.S. wrote the manuscript. L.S. and J.S. handled tools and provided supervision.

Funding sources

None.

Conflicts of interest

None.

Acknowledgments

Study supported by the Polish Society of Disaster Medicine.

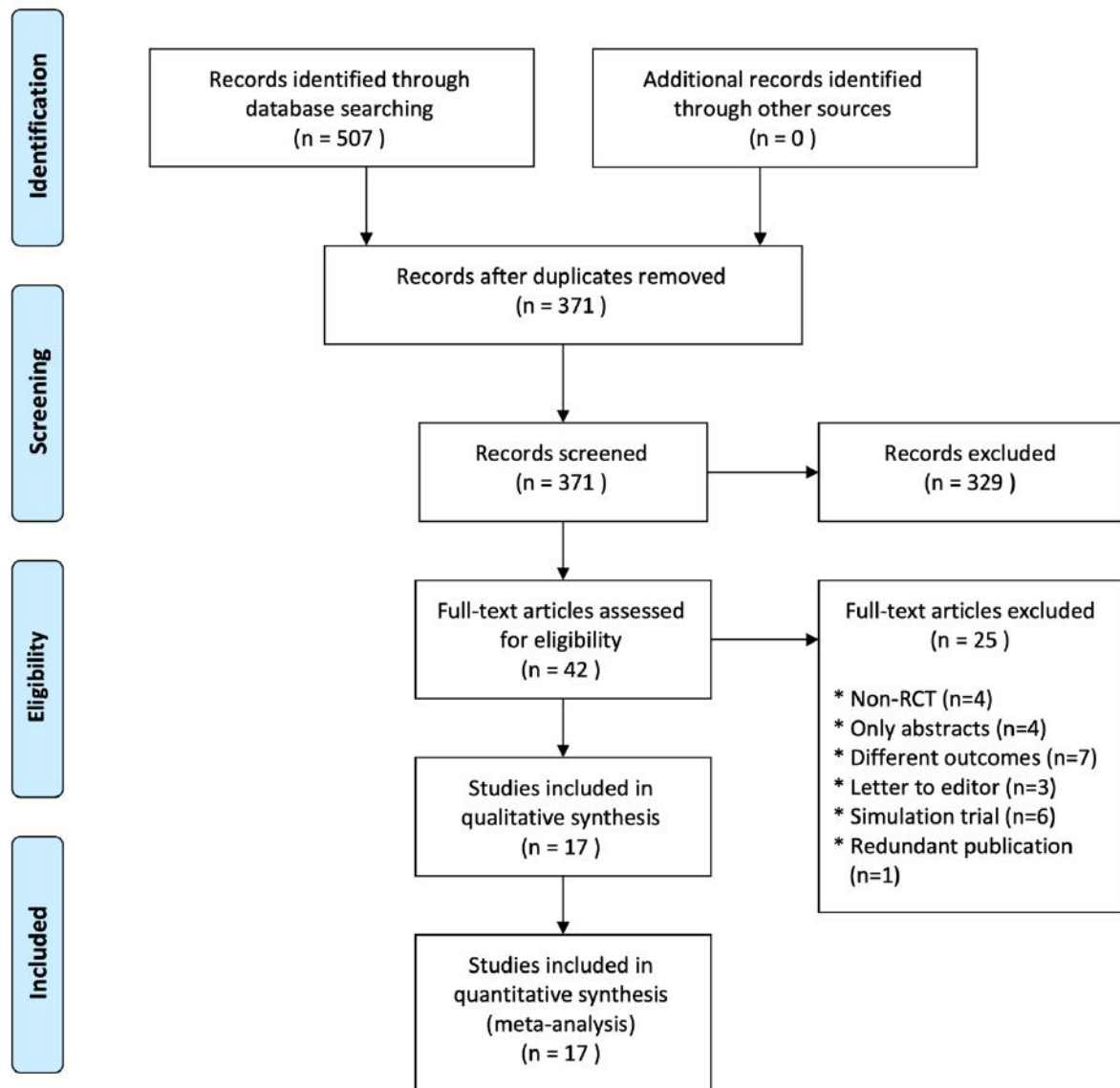


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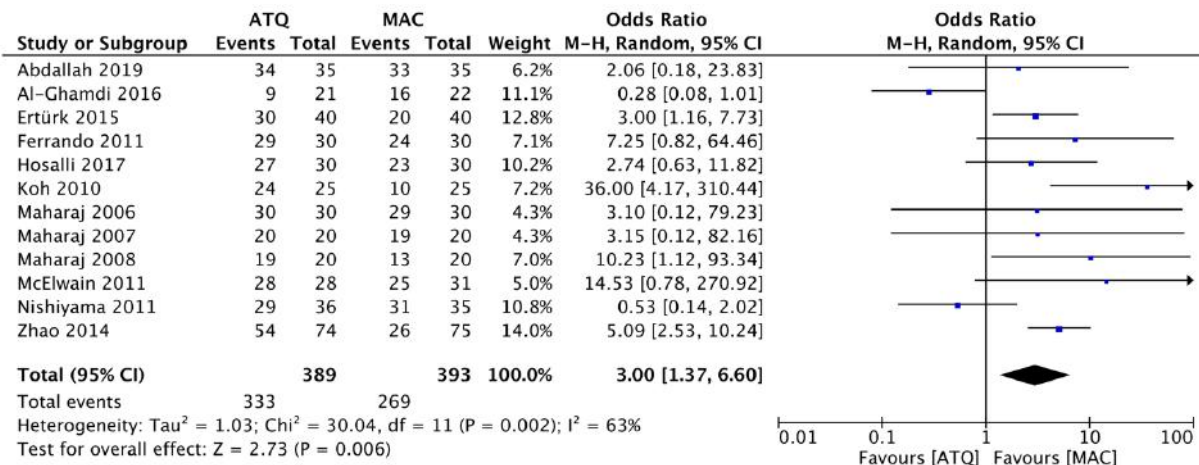


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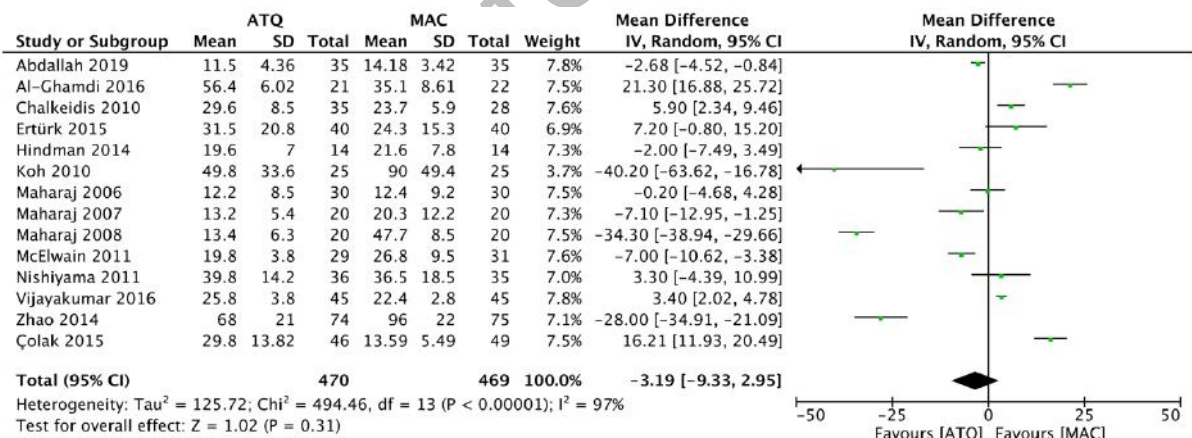


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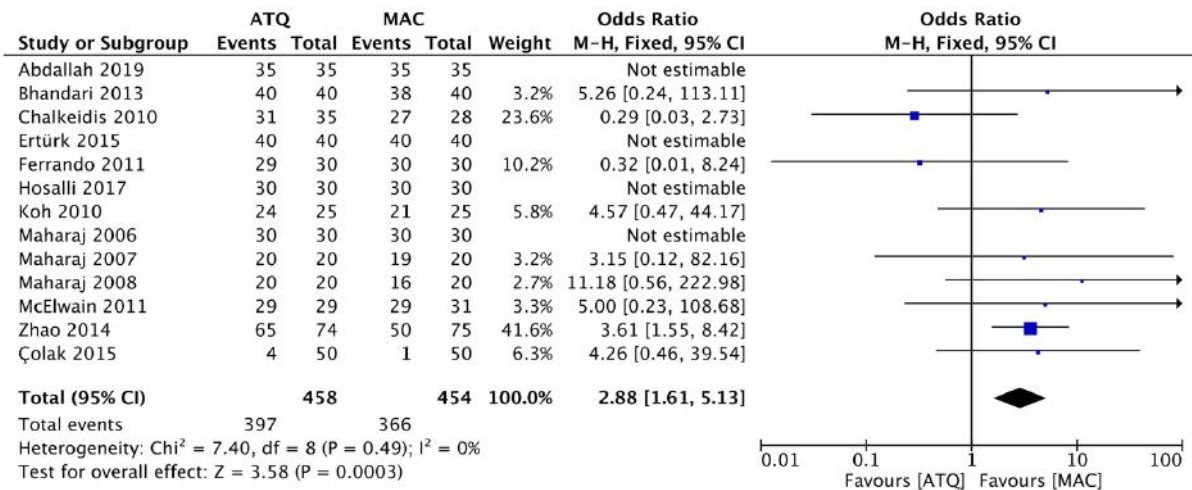


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Table 1. Characteristics of included studies.

Study	Country	Study design	Intubation setting	Operator	No. of participants		Age		Sex, male		Success of first intubation attempt	
					ATQ	MAC	ATQ	MAC	ATQ	MAC	ATQ	MAC
Abdallah et al. 2019	Egypt	Single-blinded RCT	General anesthesia	Anesthetist	35	35	40.43±9.93	41.62±5.22	19 (53.4)	22 (62.9)	34/35 (97.1)	33/35 (94.3)
Al-Ghamdi et al. 2016	Saudi Arabia	Single-blinded RCT	General anesthesia	Anesthetist	21	22	34.5±10.43	31.4±8.96	10 (47.6)	8 (36.4)	9/21 (42.9)	16/22 (72.7)
Bhandari et al. 2013	India	RCT	General anesthesia	Anesthetist	40	40	38.30±16.51	38.97±13.68	14 (35.0)	10 (25.0)	NS	NS
Chalkeidis et al. 2010	Greece	RCT	General anesthesia	Anesthetist	35	28	36.4 ± 16.4	38.5 ± 17.2	NS	NS	31/35 (88.6)	27/28 (96.4)
Çolak et al. 2015	Turkey	RCT	General anesthesia	Anesthetist	46	49	47.7±16.86	49.69±16.04	23	25	46/50 (92%)	49/50 (98.0)
Ertürk et al. 2015	Turkey	RCT	Surgery and General anesthesia	Anesthetist	40	40	38.5±15.0	40.4±13.7	25 (62.5)	26 (65.0)	33/40 (82.5)	37/40 (92.5)
Ferrando et al. 2011	Spain	RCT	Any kind of surgery	Unskillful anesthesiology residents	30	30	NS	NS	NS	NS	20/30	24/30
Hindman et al. 2014	USA	RCT cross-over	Elective surgery	Anesthetist	14	14	47±20	47±20	5 (35.7)	5 (35.7)	NS	NS
Hosalli et al. 2017	India	RCT	General anesthesia	Anesthetist	30	30	33.37±12.07	37.37±11.32	13 (43.3)	11 (36.7)	27/30 (90.0)	23/30 (76.7)
Koh et al. 2010	Korea	RCT	General anesthesia / CSI	Anesthetist	25	25	45.5 ± 7.9	44.0 ± 9.4	9 (36.0)	9 (36.0)	24/25 (96.0)	10/25 (40.0)
Maharaj et al. 2006	Ireland	Single-blinded RCT	General anesthesia	Anesthetist	30	30	43.8±16.8	41.1±16.9	11 (36.7)	11 (36.7)	30/30 (100)	29/30 (96.7)
Maharaj et al. 2007	Ireland	Single-blinded RCT	General anesthesia / CSI	Anesthetist	20	20	43.6±19.4	45.7±16.4	8 (40.0)	9 (45.0)	20/20 (100)	19/20 (95.0)

Maharaj et al. 2008	Ireland	Single-blinded RCT	General anesthesia	Anesthetist	20	20	51.7±14.6	50.2±18.2	8 (40.0)	10 (50.0)	10/20 (50.0)	13/20 (65.0)
McElwain et al. 2011	Ireland	Single-blinded RCT	General anesthesia / CSI	Anesthetist	29	31	52±19	58±20	14 (48.3)	19 (61.3)	28/29 (96.6)	25/31 (80.6)
Nishiyama 2011	Japan	RCT	General anesthesia	Anesthetist	36	35	57.9±9.9	54.3±8.5	20	19	29/36	31/35
Vijayakumar et al. 2016	India	RCT	General anesthesia	Anesthetist	45	45	35.88±11.25	34.17±10.66	14	15	45/45 (100)	45/45 (100)
Zhao et al. 2014	China	RCT	General anesthesia	Medical students	74	75	48±18	49±17	33	27	54/74	26/75

Legend: ATQ = Altraq laryngoscope; CSI = Cervical spine immobilization; MAC = Macintosh laryngoscope; RCT = Randomized control trial; NS = Not specified;

Table 2. Adverse events reported in included studies.

Type of adverse event	No. of studies	No. of incidence in ATQ group	No. of incidence in Mac group	OR (95%CI)	P value	I ² statistic
Blood staining of laryngoscope blade	2	1/64 (1.6%)	2/66 (3.0%)	0.49 (0.04, 5.61)	0.56	NA
Sore throat	3	40/96 (41.7%)	56/97 (57.7%)	0.23 (0.04, 1.20)	0.08	56%
Laryngospasm	1	0/35 (0.0%)	1/35 (2.9%)	0.32 (0.01, 8.23)	0.49	NA
Hoarseness	1	0/40 (0.0%)	0/40 (0.0%)	NA	NA	NA
Dental injury	2	0/81 (0.0%)	0/82 (0.0%)	NA	NA	NA
Muscosal trauma	1	1/21 (4.8%)	6/22 (27.3%)	0.13 (0.01, 1.22)	0.07	NA
Lips trauma	1	5/21 (23.8%)	4/22 (18.2%)	1.41 (0.32, 6.16)	0.65	NA

Legend: ATQ = Airtraq laryngoscope; MAC = Macintosh laryngoscope; OR = Odds Ratio; CI = Confidence Interval; NA = Not applicable

Airtraq® versus Macintosh laryngoscope for airway management during general anesthesia:
A systematic review and meta-analysis of randomized controlled trials

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Supplementary Table 1. Inclusion and exclusion criteria of included studies.

Study	Inclusion criteria	Exclusion criteria	Outcome(s)	Findings
Abdallah et al. 2019	18–60 years old, with the American Society of Anesthesiologists physical status class I or II, having no criteria for suspected difficult intubation, scheduled for various types of nonophthalmic elective surgery requiring orotracheal intubation.	Patients with raised IOP or intracranial pressure, suspicion of difficult intubation, need for rapid sequence induction, gastric acid aspiration risk, suspicion or history of difficult intubation, cervical spine pathology, body mass index ≥ 35 , cardiovascular, hyperreactive airway disease, and/or on β -blocker therapy	intubation time, first-attempt success rate, time to best laryngoscopic view, and percentage of glottic opening (POGO) score	In comparison to the Macintosh laryngoscope, Airtraq conferred significantly better intubation criteria and lesser stress response to laryngoscopy and intubation.
Al-Ghamdi et al. 2016	Patients aged 18 to 65 years, with an ASA physical status classification of I to II, who were scheduled for elective surgery and whose anesthesia plan included routine orotracheal intubation	Patients with an anticipated or known difficult intubation such as history of cervical spine injury or surgery; limited neck mobility; previous oral or throat surgery or difficult direct laryngoscopy; a Body Mass index >35 kg/ m ² ; or missing incisor teeth	Time to tracheal intubation. Secondary outcomes included the laryngoscopic view, numbers of laryngoscopy attempts, first-pass success rate, optimization maneuvers, ease of intubation, and postoperative sore throat.	The Airtraq® require longer intubation times, as primary outcome, and cause less sore throat than the Macintosh when used by anesthesiologists with limited experience in patients with normal airways.
Bhandari et al. 2013	ASA physical status I and II, age group 16-65 years of either sex, patients with head injury, psychiatric disorder, respiratory tract (oropharynx, larynx) pathology, endocrine disorder, predicted difficult airway (such as mouth opening <2 cm, modified MPS class 3 and 4, BMI > 35 kg/m ² .	Gastroesophageal reflux disease, hiatus hernia, and pregnancy.	Overall success rate of tracheal intubation, overall duration of successful tracheal intubation, optimization maneuvers, POGO score and ease of intubation.	Both Airtraq and Macintosh laryngoscopes are equally effective in tracheal intubation in normal airways. Duration of successful tracheal intubation was shorter in the Airtraq group which was statistically significant.
Chalkeidis et al. 2010	ASA status I–III	(1) patients requesting regional anesthesia; (2) the need for endotracheal tubes that are armored, cranial-facing or caudal-facing, or the need for a nasotracheal tube, as indicated by the type of surgery; (3) history of an impossible or difficult intubation; (4) emergency surgery.	The time needed for intubation, any assistance required, complications during and after laryngoscopy and intubation, and the number of unsuccessful intubation attempts.	The Airtraq laryngoscope is easier to use but it does not have any significant advantages compared with the Macintosh laryngoscope for routine airway management.

Çolak et al. 2015	ASA status of I to III, and who were aged between 20 and 75	a history of emergency intubation or difficult intubation, a body mass index higher than 35 or a rheumatologic disease that causes limitation of cervical motion, a previous history of cervical operation or tumor, trauma or infection on upper airway, and the absence of teeth. Anthropometric measurements such as tiromental (thyroidea and gnathion) and sternomental (sternal and gnathion) distances, inter-incisor gap (between the lower and upper incisor teeth), neck circumference (at the level of the thyroid cartilage), and lower face height (between gnathion and subnasale) were measured and recorded by an anatomist the night before the operation.	The extension angle during intubation and the Cormack-Lehane Score	A minimal cervical motion was obtained during tracheal intubation with the use of Airtraq® laryngoscope compared with the Macintosh laryngoscope.
Ertürk et al. 2015	ASA I-II, 18-65 years old	Pregnant women; patients with gastroesophageal reflux, delayed gastric emptying; severe respiratory and cardiovascular problems; those who had intraoral, neck, pre-planned emergency, neck dissection, larynx and thyroid surgeries; those who had failed intubation despite three successful attempts and those who refused to be a part of this study	Patients' snoring complaints, modified Mallampati scores, sternomental distances, thyromental distance, interincisor distance measurements and Cormack-Lehane (C-L) laryngoscopic classification, upper lip bite test results, intubation time, number of intubation attempts, maneuvers and techniques used for facilitating intubation and complications arising from intubation	In cases with seemingly difficult intubations, we believe the Airtraq laryngoscope has an advantage over the Macintosh laryngoscope, owing to its better view of the oropharyngeal and glottic areas in addition to facilitating intubation in patients with limited head extension.
Ferrando et al. 2011	Patients scheduled for any kind of surgery who required tracheal intubation	Patients who could require rapid sequence induction, ASA physical status 4, age under 18 yr, and an interincisor distance less than 3 cm	The Cormack-Lehane score, the success rate at first intubation attempt, and the laryngoscopy and intubation times.	The Airtraq is a useful laryngoscope in unskilful anesthesiology residents improving the laryngeal view

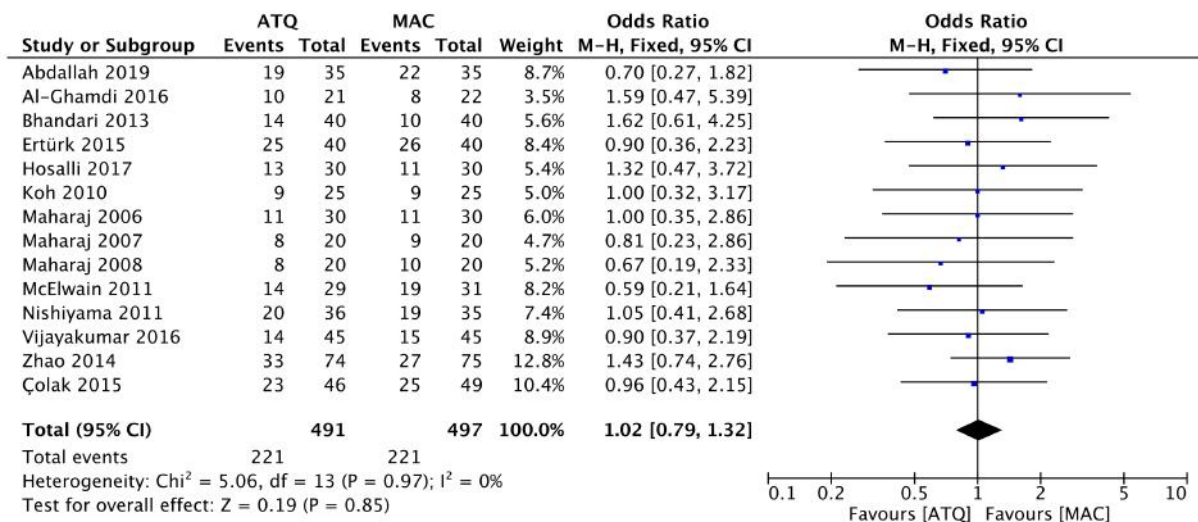
					and, therefore, facilitating the tracheal intubation.
Hindman et al. 2014	(1) Mallampati airway class I or II, (2) thyromental distance of 6.0 cm or greater, and (3) sterno-mental distance of 12.5 cm or greater.; (4) age 18 to 80 yr, (6) height between 1.52 and 1.83 m, and (6) body mass index of 30.0 kg/m ² or less.	(1) maxillary incisors that were loose or poor condition, (2) previous difficult intubation, (3) any cervical spine anatomic abnormalities such as disc disease, instability, myelopathy, and/or any previous cervical spine surgery, (4) symptomatic gastroesophageal reflux or reactive airway disease, (5) any history of coronary artery disease or cerebral aneurysm, regardless of symptom status, (6) any history of vocal cord and/or glottic disease or dysfunction, (7) preoperative systolic blood pressure greater than 180 mmHg or diastolic blood pressure greater than 80 mmHg, and (8) ASA physical status class greater than 3.	(1) maximal laryngoscope force application, and (2) maximal overall (Oc-C5) cervical spine motion (extension).	Cervical spine motion is affected by the amount of force applied by the laryngoscope but shows that intubation biomechanics are nonlinear and differ markedly between laryngoscopes. Although intubation with the Airtraq required only 20% of the force required by the Macintosh (~10 vs. ~50 N), it resulted in 67% as much Oc-C5 motion (~20 vs. ~30 degrees).	
Hosalli et al. 2017	ASA physical status I–II patients, aged 18–60 years, scheduled for various elective surgeries under general anaesthesia requiring tracheal intubation.	Patients with risk factors for difficult intubation (modified Mallampati class III and IV, thyromental distance <6 cm, interincisor distance <3 cm, body mass index more than 30 kg/m ²), risk for gastric aspiration, relevant drug allergy.	(1) The difficulty of tracheal intubation based on intubation difficulty scale (IDS) score; (2) glottic view according to Cormack-Lehane grading; (3) number of optimization techniques (use of bougie, different size blade, stylet) (4) impact on haemodynamic variables such as heart rate (5) mean arterial blood pressure; (6) and oxygen saturation, which were recorded preintubation, 1, 3 and 5 min after intubation	In patients undergoing endotracheal intubation with cervical immobilisation, Airtraq™ laryngoscope was superior to the Macintosh laryngoscope, with greater ease of intubation and lower impact on haemodynamic variables.	
Koh et al. 2010	Patients aged 20 to 60 years, with ASA physical status I-II who were scheduled	The risk factors for increased dental injury, pulmonary aspiration, functional or anatomical deformities in the airway	Intubation time, success rate of first intubation attempt, number of intubation attempts,	The Airtraq offers a better laryngeal view and higher success rate at first intubation	

	to undergo surgical procedures necessitating tracheal intubation.	(i.e., asthma, burn, and tumor), anticipated airway difficulties (i.e., Mallampatti grade IV or having prior history of difficult airway), and body mass index greater than 30. Patients were also excluded if surgery required one lung ventilation or a different endotracheal tube other than the conventional endotracheal tube used.	and percentage of glottic opening (POGO) score.	attempt in patients who are applied with a Philadelphia cervical collar due to suspicion of cervical spine injury.
Maharaj et al. 2006	ASA physical status I–III patients, aged 18 years of age or older, scheduled for surgical procedures requiring tracheal intubation	Risk factors for gastric aspiration and /or risk factors for difficult intubation (Mallampatti class III or IV; thyromental distance less than 6 cm; interincisor distance less than 4.0 cm) were present or where there was a history of relevant drug allergy.	The duration of the tracheal intubation procedure and the intubation difficulty scale (IDS) score. A secondary endpoint was the rate of successful placement of the tracheal tube (ETT) in the trachea.	The Airtraq® laryngoscope offers a new approach for the management of the normal airway. The Airtraq® reduced the difficulty of tracheal intubation and the degree of haemodynamic stimulation compared to the Macintosh laryngoscope in patients at low risk for difficult laryngoscopy and intubation.
Maharaj et al. 2007	ASA physical status I–III, aged 18 yr or older, scheduled to undergo surgical procedures necessitating tracheal intubation.	Risk factors for gastric aspiration and/or difficult intubation (Mallampati class III or IV, thyromental distance less than 6 cm, interincisor distance less than 4.0 cm) were present, or where there was a history of relevant drug allergy.	The duration of the tracheal intubation procedure and the IDS score. A secondary endpoint was the rate of successful placement of the ETT in the trachea.	Authors demonstrate the utility of the Airtraq laryngoscope for tracheal intubation in patients with cervical spine immobilization.
Maharaj et al. 2008	ASA physical status 1–3 patients, aged 18 years of age or older, who were deemed on pre-operative assessment by their primary anesthetist to be at increased risk for difficult tracheal intubation and scheduled for surgical procedures requiring tracheal intubation. Inclusion criteria consisted of possession of at least three of the following criteria:	NS	The duration of the tracheal intubation procedure and the IDS score. A secondary endpoint was the rate of successful placement of the tracheal tube in the trachea.	Tracheal intubation with the Airtraq also reduced the degree of haemodynamic stimulation and minor trauma compared to the Macintosh laryngoscope.

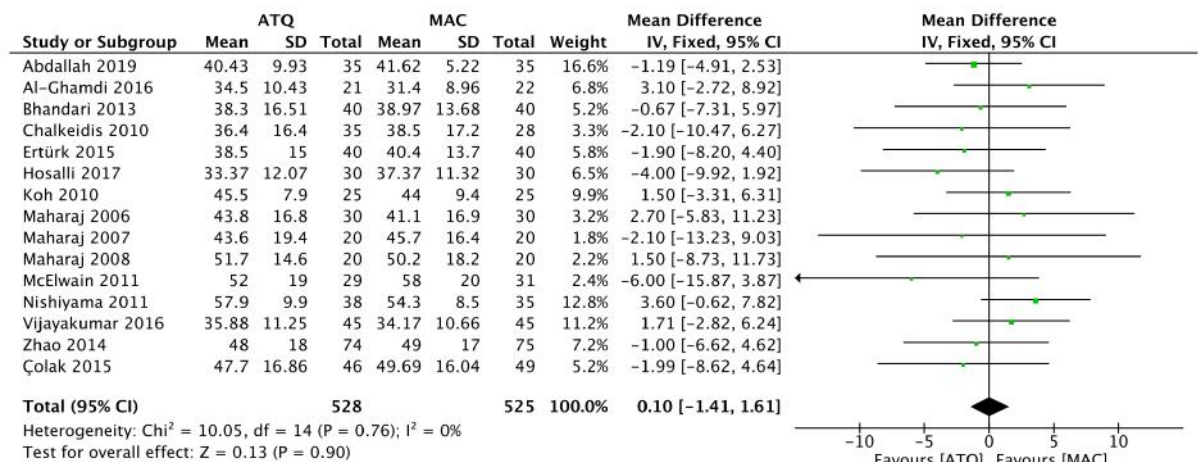
	(1) thyromental distance < 6 cm; (2) Mallampatti classification 3 or 4; (3) interincisor distance < 4 cm; (4) previously documented difficult intubation.			
McElwain et al. 2011	ASA physical status I – III patients, aged 16 yr or older, undergoing surgical procedures requiring tracheal intubation.	Risk factors for gastric aspiration, difficult intubation, or both (Mallampati class III or IV; thyromental distance ,6 cm; inter-incisor distance ,3,5 cm) were present, or where there was a history of relevant drug allergy.	The intubation difficulty scale (IDS) score. Secondary endpoints were the duration of the laryngoscopy attempt, duration of the tracheal intubation procedure, the total time required to secure the airway, and the rate of successful placement of the TT in the trachea.	The Airtraq® laryngoscope performed better than the Macintosh laryngoscopes in patients undergoing cervical immobilization
Nishiyama 2011	ASA physical status I or II scheduled for general anesthesia aged 30 to 70 years.	History of surgery or any other diseases of neck and face.	Number of the attempts), and the time required for successful tracheal intubation.	The MAC and ATQ were better than the AWS-Miller for patients with easy intubation, while the ATQ was better than the MAC for difficult intubation when the expert anesthesiologists did the intubation.
Vijayakumar et al. 2016	Adult patients aged 18 to 60 years of either sex belonging to ASA 1 and 2, with normal airway parameters undergoing elective abdominal, urological, and gynecologic surgeries under general anesthesia requiring endotracheal intubation	Patients at risk for gastric aspiration, anticipated difficult airway (previous history/documentated difficult intubation, interincisor distance of <3 cm, bucked tooth, Modified Mallampatti classification III/IV, thyromental distance of <6 cm, restricted neck extension, patient who cannot bring mandibular incisors anterior to maxillary incisors, any gross abnormality of head and neck, and obese with body mass index (BMI) ≥ 30kg/m2).	Successful intubation, and degree of difficulty of intubation as assessed by Intubation Difficulty Scale (IDS) score. Secondary outcomes compared were duration of laryngoscopy and intubation, degree of difficulty of intubation as assessed by Numerical Rating Scale score, soft tissue, and dental trauma.	In anesthetized adult patients with MILS compared with Macintosh, Airtraq provides equal success rate of intubation, statistically significant (although clinically insignificant) longer duration for laryngoscopy and intubation. Intubation with Airtraq was significantly easier than Macintosh as assessed by the IDS score.

Zhao et al. 2014	ASA physical status I to II patients, aged between 18 and 65 years old, scheduled for surgical procedures requiring general anaesthesia and tracheal intubation.	A history or any indicator of a difficult airway (i.e. Mallampati grade >2, obesity (body mass index >30 m/kg ²), interincisor distance less than 4 cm), or any risk factor of pulmonary aspiration.	Success rate of intubation using each laryngoscope. The number of optimization maneuvers required to perform tracheal intubation. Dental trauma, visible trauma to lip or oral mucosa, and presence of blood on laryngoscope blade were also recorded.	Airtraq laryngoscope is easier to master for novice personnel with a higher intubation success rate and shorter intubation duration compared with the Macintosh laryngoscope.
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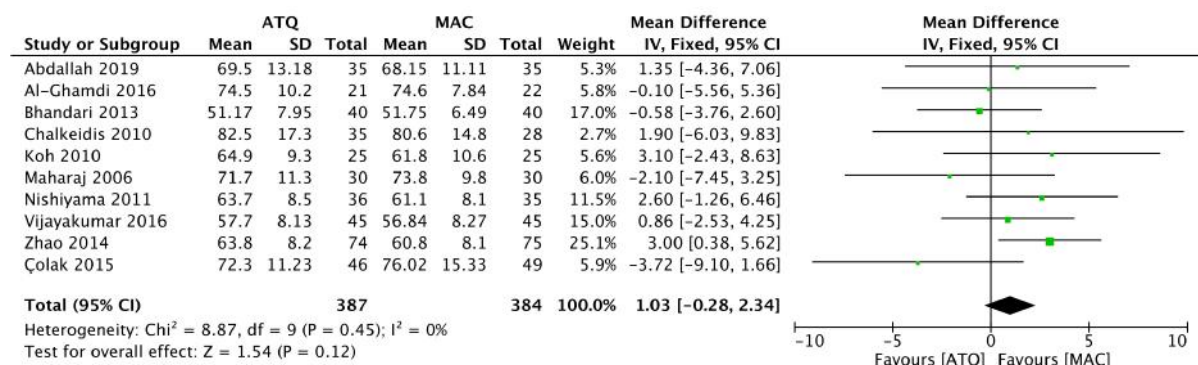
Legend: ASA = American Society of Anesthesiologists; NS = Not specified;



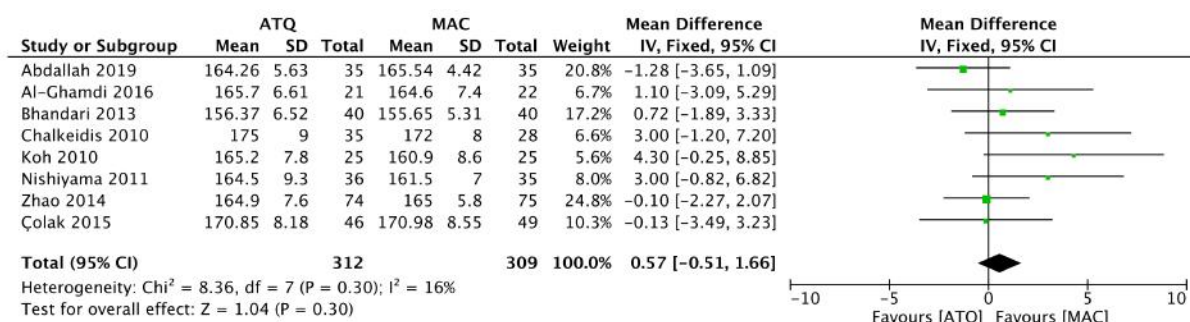
Suppl. Fig. 1. Forest plot of gender of participants (male) in Airtraq vs. Macintosh groups.



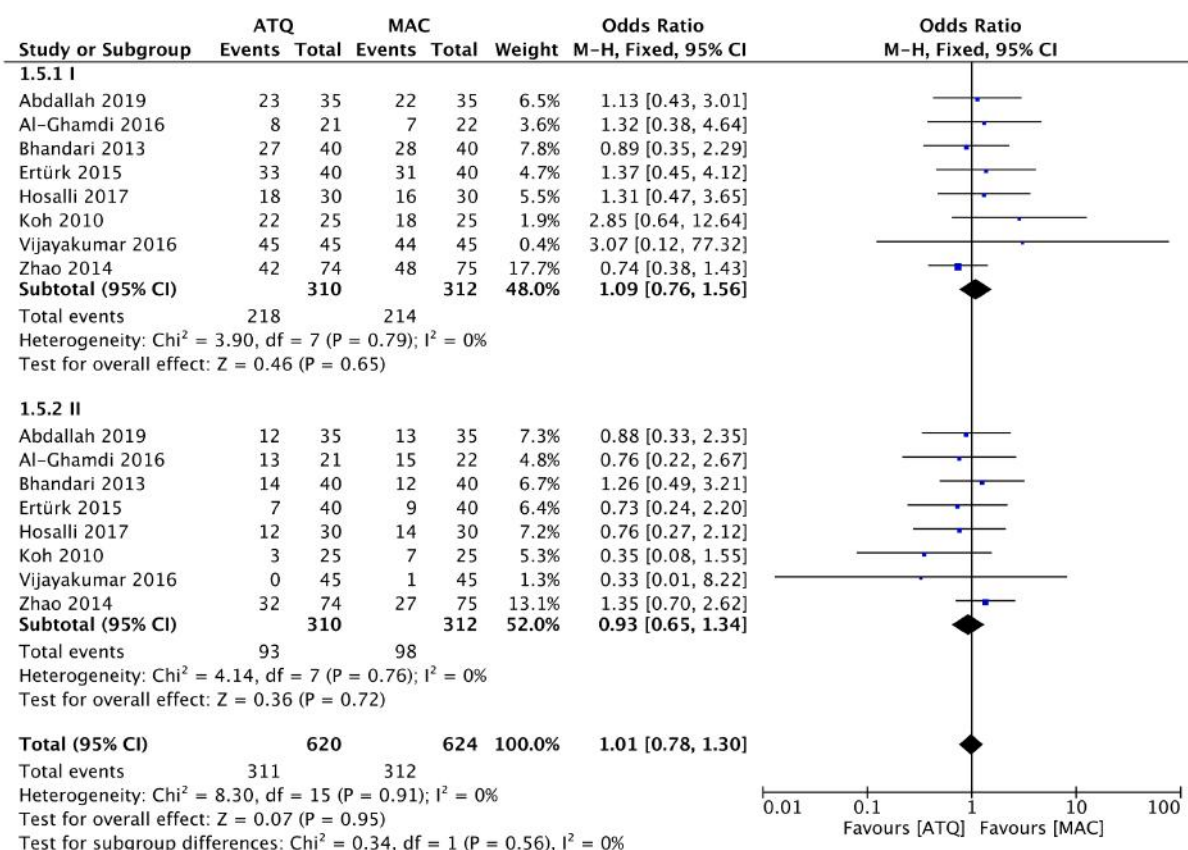
Suppl. Fig. 2. Forest plot of age in Airtraq vs. Macintosh groups.



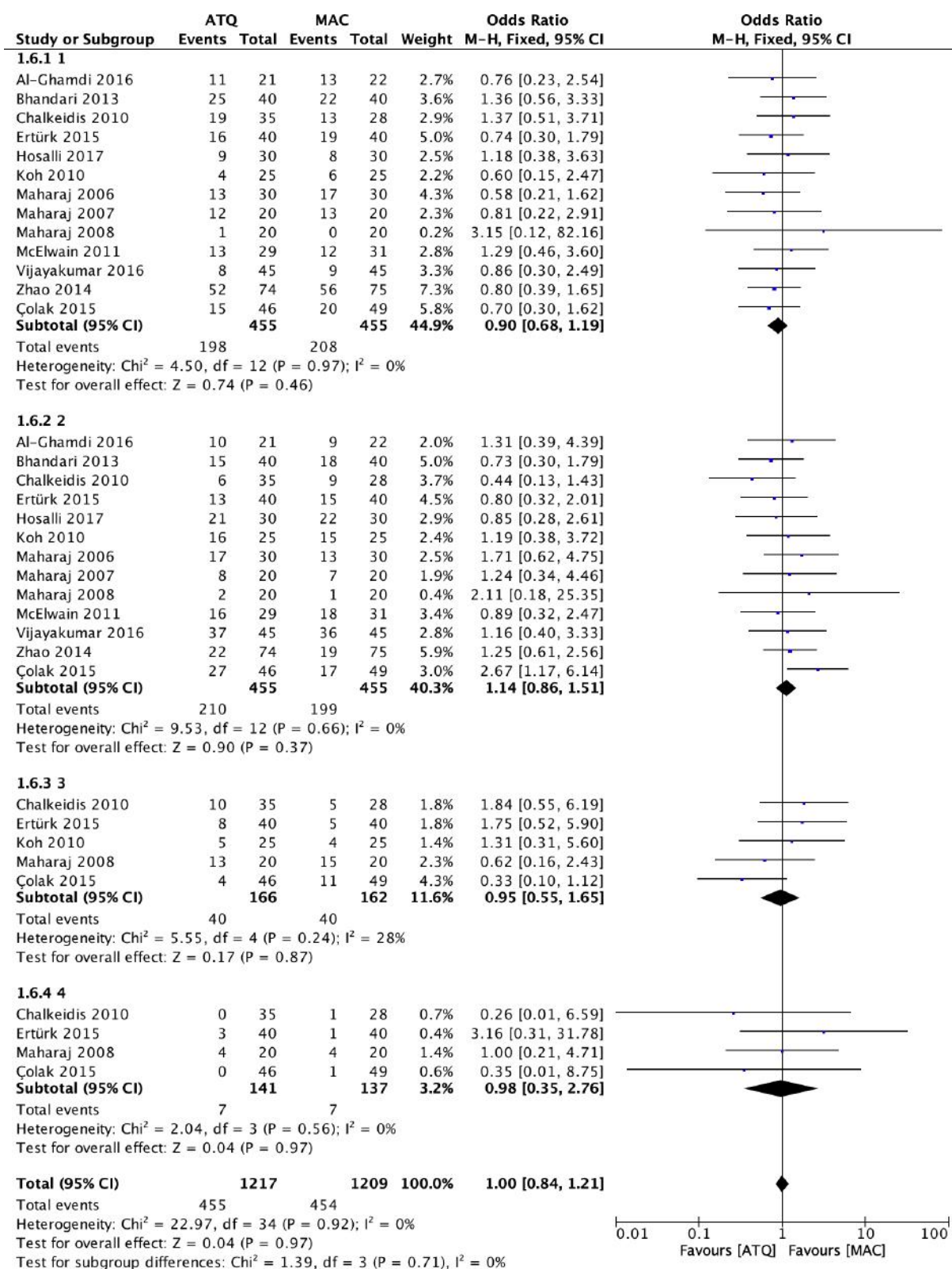
Suppl. Fig. 3. Forest plot of weight [kg] in Airtraq vs. Macintosh groups.



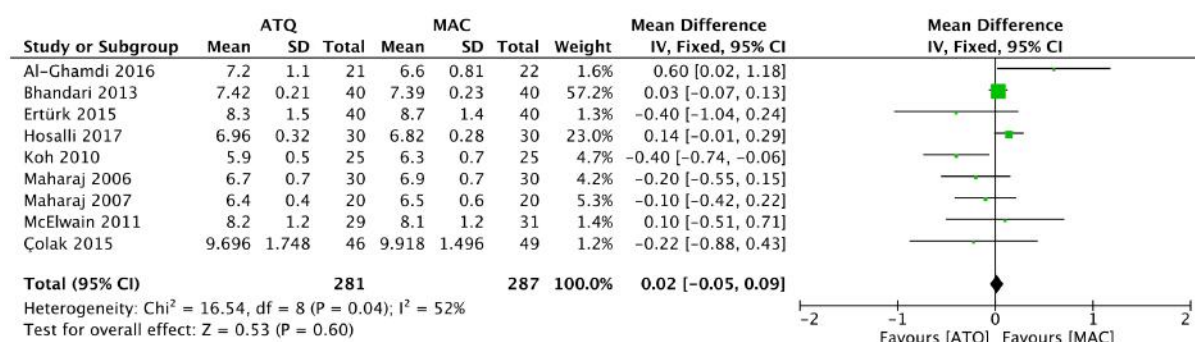
Suppl. Fig. 4. Forest plot of height [cm] in Airtraq vs. Macintosh groups.



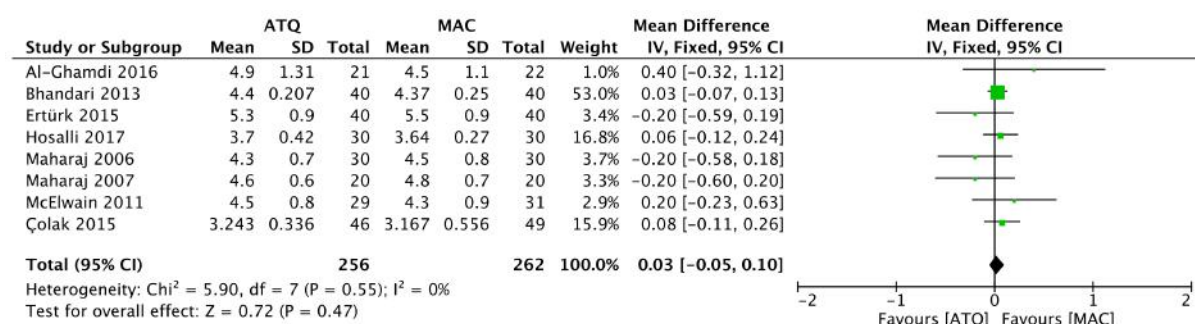
Suppl. Fig. 5. Forest plot of the American Society of Anesthesiologists physical status in Airtraq vs. Macintosh groups.



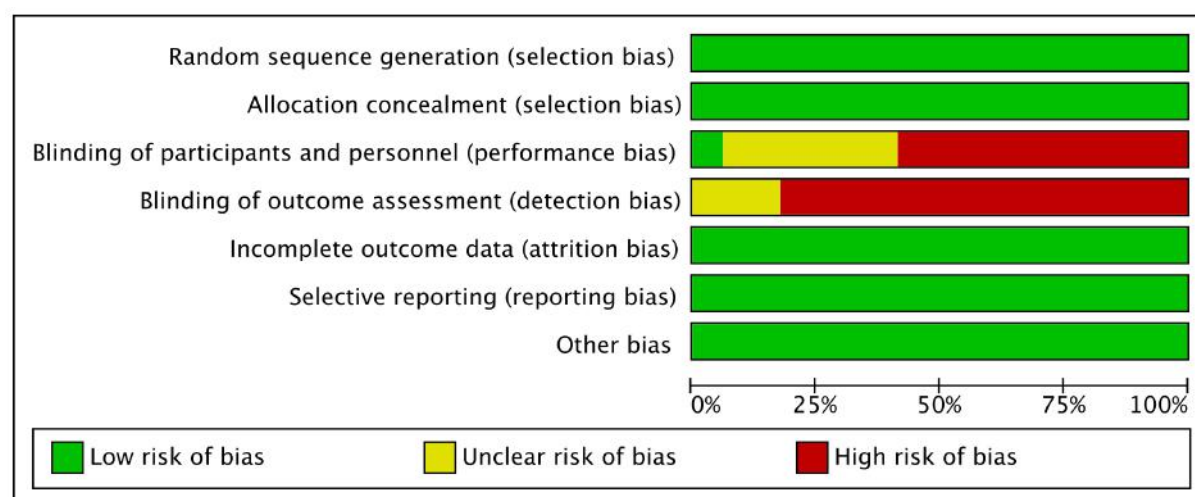
Suppl. Fig. 6. Forest plot of gender of Mallampati classification in Airtraq vs. Macintosh groups.



Suppl. Fig. 7. Forest plot of Thyromental distance in Airtraq vs. Macintosh groups.



Suppl. Fig. 8. Forest plot of Inter-incisor distance in Airtraq vs. Macintosh groups.



Suppl. Fig. 9. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Abdallah 2019	+	+	?	?	+	+	+
Al-Ghamdi 2016	+	+	?	?	+	+	+
Bhandari 2013	+	+	-	-	+	+	+
Chalkeidis 2010	+	+	-	-	+	+	+
Çolak 2015	+	+	-	-	+	+	+
Ertürk 2015	+	+	-	-	+	+	+
Ferrando 2011	+	+	-	-	+	+	+
Hindman 2014	+	+	+	?	+	+	+
Hosalli 2017	+	+	-	-	+	+	+
Koh 2010	+	+	-	-	+	+	+
Maharaj 2006	+	+	?	-	+	+	+
Maharaj 2007	+	+	?	-	+	+	+
Maharaj 2008	+	+	?	-	+	+	+
McElwain 2011	+	+	?	-	+	+	+
Nishiyama 2011	+	+	-	-	+	+	+
Vijayakumar 2016	+	+	-	-	+	+	+
Zhao 2014	+	+	-	-	+	+	+

Suppl. Fig. 10. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

VIESCOPE® LARYNGOSCOPE VERSUS MACINTOSH LARYNGOSCOPE DURING DIFFICULT INTUBATION PERFORMED BY PARAMEDICS: A RANDOMIZED CROSS-OVER MANIKIN TRIAL

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ABSTRACT

INTRODUCTION: The aim of this study was to evaluate intubation performance by paramedics using Macintosh laryngoscope and VieScope® laryngoscope under simulated difficult airway conditions.

METHODS: In a randomized, single-blinded, cross-over simulation trial, 42 paramedics performed endotracheal intubation using VieScope® and Macintosh (MAC) laryngoscopes in two difficult airway scenarios: (A) tongue edema, (B) manual cervical inline stabilization. The order of participants and intubation methods was random. Time to ventilation constituted the primary outcome, and the secondary outcomes were the success rate of first intubation attempt, overall intubation success rate, Cormack and Lehane grade, and ease of use.

RESULTS: In scenario A, the median overall intubation time was 55s (46–109) in the MAC group and 30.5s (26–35) in the VieScope® group ($p < 0.001$). The efficacy of the first intubation attempt with MAC and VieScope® varied and amounted to 64.3% vs. 95.2% ($p < 0.001$). During scenario B, VieScope® offered better intubation conditions than MAC ($p < 0.001$), including shorter intubation time, higher first attempt and overall intubation success rates, as well as better glottic view.

CONCLUSIONS: In this simulation trial, we found that VieScope® could be successfully used for intubation in difficult airways by paramedics with little simulation experience with this device. VieScope® was associated with shorter time and higher success rates of intubation attempt compared with MAC. Nevertheless, we recommend that the performance of VieScope® and MAC should be further evaluated in the clinical setting to confirm our results.

KEY WORDS: endotracheal intubation, difficult airway, VieScope® laryngoscope, channelled laryngoscope, medical simulation, paramedic

Disaster Emerg Med J 2020; 5(3): 134–141

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INTRODUCTION

Endotracheal intubation is still considered the gold standard of airway protection in many clinical situations. It occupies a special place in emergency medicine in-hospital as well as pre-hospital conditions. In pre-hospital conditions, endotracheal intubation is associated with the risk of hypoxia, tracheal tube misplacement, esophageal intubation, hypotension, vomiting and aspiration, cardiac arrhythmia, dental injury, or bleeding [1]. Rapid, uncomplicated, and accurate placement of the tracheal tube is one quality indicator of good advanced airway management [2]. In accordance with many society guidelines, endotracheal intubation must be performed by the most experienced operator in the team [3].

Emergency intubation based on direct laryngoscopy arouses a high risk of failure. As many authors indicate, the effectiveness of the first intubation attempt with a Macintosh laryngoscope is 57.6% [4], 84.4% [5], 89.94% [6]. The issue concerns not only adults but also pediatric patients [7]. In pre-hospital situations, the effectiveness of intubation may be even lower owing to the conditions under which intubation is performed and the experience of medical staff. As Crewdson et al. [8] indicate in their meta-analysis, only 14,913 intubations out of the total of 19,178 (77.8%) were successful at the first attempt. Rognås et al. [9] report that following rapid sequence intubation, the incidence of first-pass success was 85.8% and the overall incidence of complications equaled 22.0%, with the incidence of hypotension of 7.3% and that of hypoxia of 5.3%. Therefore, it is reasonable to search for alternative methods of endotracheal intubation to direct laryngoscopy, which will allow for more efficient performance of the medical procedure by paramedics and other medical personnel.

The aim of this study was to evaluate intubation performance by paramedics using Macintosh laryngoscope and VieScope® laryngoscope under simulated difficult airway conditions. We hypothesized that the intubation time in the case of paramedics using VieScope® would be superior to that for Macintosh laryngoscope.

MATERIAL AND METHODS

Study design

We conducted a randomized, single-blinded, cross-over simulation trial to evaluate intubation conditions

when using VieScope® and Macintosh laryngoscopes in difficult airway scenarios. The study was performed between November 2019 and February 2020. The study protocol was approved by the Institutional Review Board of the Polish Society of Disaster Medicine (approval No.: 15.11.2019.IRB). The Consolidated Standards of Reporting Trials (CONSORT) statement was applied (see Supplementary Tab. 1) [10].

Participants

The study involved 42 paramedics who had no experience in endotracheal intubation with VieScope® but had experience in intubation with Macintosh laryngoscope. Voluntary written informed consent was obtained from each participant. All participants were active paramedics and worked in an Emergency Medical Services team in Poland.

Equipment and materials

Two types of laryngoscope were used in the study: a standard Macintosh laryngoscope with blade #3 (HEINE Optotechnik GmbH & Co. KG, Gilching, Germany) and a new VieScope® laryngoscope (Adroit Surgical, Oklahoma City, USA; see Fig. 1). VieScope® laryngoscope is a self-contained, battery-powered, disposable scope that takes advantage of a closed circular tube with a beveled end to visualize the vocal cords. The light is transmitted through the sidewall of the tube from end to end as well as within the lumen of the tube to give the user the best illumination of the target tissue with minimal chance of light obstruction by secretions or blood. Endotracheal intubation with VieScope® involved a two-step process. Firstly, the device was inserted orally to obtain visualization of glottis through the clear cylindrical lumen of the intubation channel. The second step involved a bougie



FIGURE 1. VieScope® laryngoscope

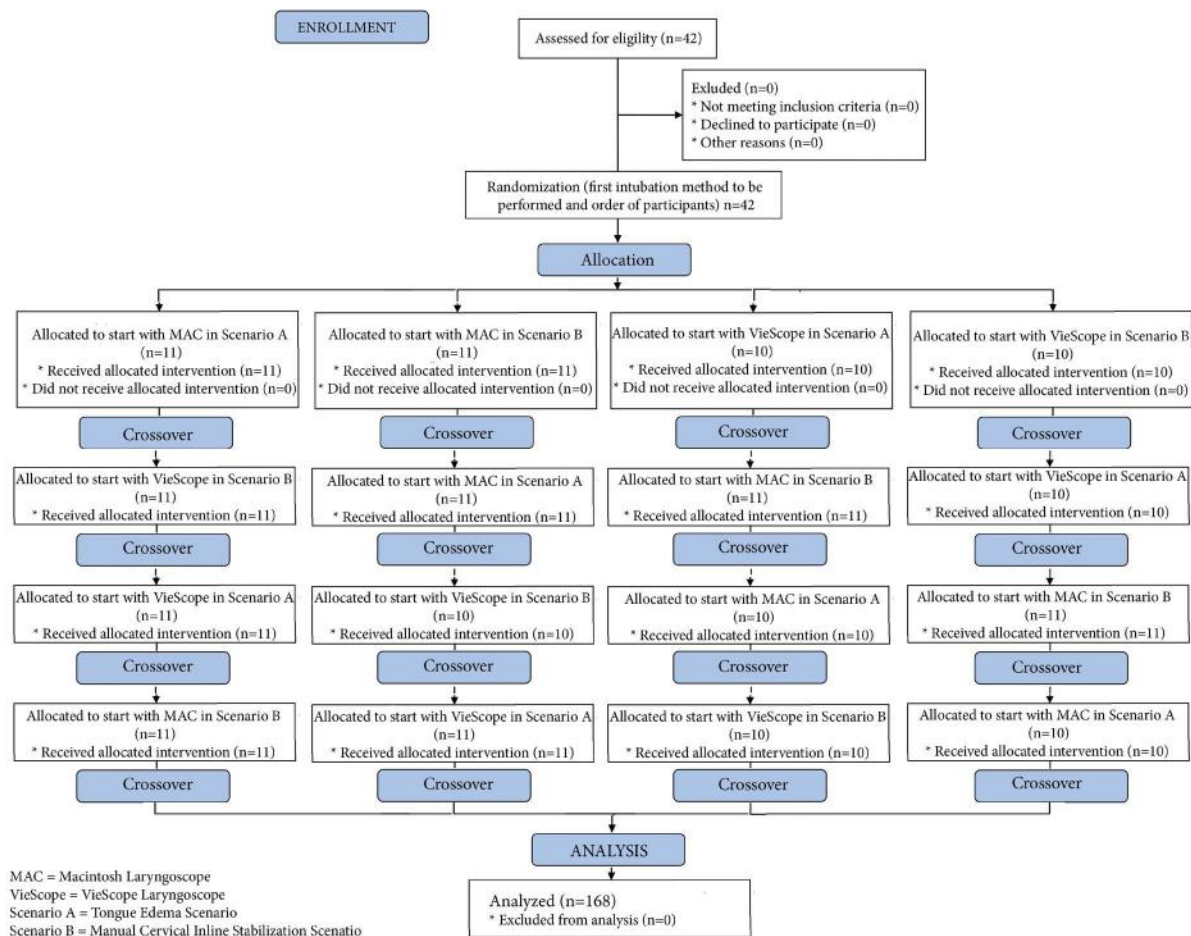


FIGURE 2. Randomization flow chart

guide insertion and removal of VieScope® followed by railroading the endotracheal tube over the bougie. The Voir Bougie guide size 15 Fr is dedicated to VieScope®. For intubation with Macintosh laryngoscope, a standard intubation stylet was used. In each case, the stylet, guide, and tube were covered with a lubricant dedicated for simulators.

Interventions

All participants listened to a 30-min lecture covering anatomical and physiological basics, as well as principles of endotracheal intubation with the particular devices. At the end of the theoretical part, the instructor demonstrated correct endotracheal intubation with VieScope® and Macintosh laryngoscopes. Afterwards, the paramedics had an opportunity to participate in a workshop session, during which they performed endotracheal intubation using the two types of investigated laryngoscopes under normal airway conditions. To this pur-

pose, an AirSim Combo Bronchi X airway simulator (TrueCorp®, Ireland) was used.

One month later, the 42 paramedics participated in the proper evaluation. With the use of the Research Randomizer program (randomizer.org), they were randomized into individual groups. The order of both participants and intubation methods was random. The detailed randomization procedure is presented in Figure 2. An advanced SimMan 3G adult patient simulator (Laerdal, Stavanger, Norway) was used to simulate a patient requiring intubation. The simulator was placed on a flat floor in the neutral position. The paramedics were asked to perform endotracheal intubation using the VieScope® and Macintosh laryngoscopes in two separate difficult airway scenarios:

- scenario A: tongue edema (simulated by inflating the tongue using the simulator software);
- scenario B: manual cervical inline stabilization.

All participants performed a maximum of three intubation attempts with each device in the differ-

Table 1. Data from intubation in Scenario A: Tongue edema. Data are presented as median (IQR), or as number (percentage)

Parameter	Macintosh laryngoscope	VieScope®	p-value
Duration of intubation when one attempt needed, s	48.5 (44–58)	30 (23–39)	< 0.001
Overall intubation time, s	55 (46–109)	30.5 (26–35)	< 0.001
Overall success rate (%)	39 (92.9)	42 (100)	0.081
Number of intubation attempts (%)			
1	27 (64.3)	40 (95.2)	< 0.001
2	5 (11.9)	2 (4.8)	
3	7 (16.7)	–	
Median (IQR)			
Cormack & Lehane grade			< 0.001
1	–	31 (73.8)	
2	10 (23.8)	11 (26.2)	
3	30 (71.4)	–	
4	2 (4.8)	–	
Ease of use (0–10; VAS score)	5 (3–7)	0 (0–3)	< 0.001

IQR — Interquartile Range

ent airway scenarios, with a 10-min break between the scenarios.

Outcomes

The primary outcome was time to first ventilation required by one intubation attempt, defined as the time from picking up the laryngoscope to the first visible ventilation of the lungs in the absence of gastric infiltration. Besides, overall intubation time was calculated, defined as the sum of times of individual intubation attempts where more than one intubation attempt was needed. The secondary outcomes were the success rate of first intubation attempt, overall intubation success rate, Cormack and Lehane grade, and ease of use [11]. Each airway scenario was limited to a maximum of 60 s, up to 3 intubation attempts. Between the airway scenarios, the paramedics had a break lasting 10 min. Following the completion of a scenario, the subjects were asked to grade each device for the ease of its technical use (0 — easy, 10 — difficult).

Statistical analysis

The results obtained for 10 paramedics in the preliminary study showed that the time required for successful intubation with VieScope® was approximately 27 ± 5 s. We estimated that 41 participants would be adequate for 2 independent groups with $\alpha = 0.05$ and $\beta = 0.2$.

All statistical analyses were performed with the use of the Statistica 13.3EN for Windows software (Tibco Inc.; Tulsa, USA). Qualitative variables are

presented as absolute values and relative frequencies. Numerical variables are presented as means and standard deviations or medians and interquartile ranges. The relationship between categorical variables was analyzed with the Fisher exact test and the McNemar test. For numerical variables, the parametric and non-parametric tests applied were Student's *t*-test, the Wilcoxon test, and the Mann-Whitney test. A two-tailed *p*-value of 0.05 was considered significant.

RESULTS

Overall, 42 paramedics (15 women, 35 men; age: 32 (27–36) years; work experience: 6 (3–10) years participated in the trial. All participants had clinical experience in endotracheal intubation with Macintosh laryngoscope.

Tongue edema

The intubation time when only one intubation attempt was required equaled 48.5 s (44–58) for Macintosh laryngoscope vs. 30 s (23–39) for VieScope® ($p < 0.001$; Tab. 1). The total intubation time for Macintosh and Vie Scope® laryngoscopes varied and amounted to 55 s (46–109) vs. 30.5 s (26–35), respectively. The efficacy of the first intubation attempt with VieScope® was significantly higher than that for Macintosh laryngoscope (95.2% vs. 64.3%; $p < 0.001$). The total efficacy was comparable between the intubation methods and equaled 100% for Vie Scope® and 92.9% for Macintosh

Table 2. Data from intubation in Scenario B: Manual cervical inline stabilization. Data are presented as median (IQR), or as number (percentage)

Parameter	Macintosh laryngoscope	VieScope®	p-value
Duration of intubation when one attempt needed, s	49 (39–52)	30 (24–34)	< 0.001
Overall intubation time, s	88 (51–114)	30.5 (24–35)	< 0.001
Overall success rate (%)	41 (97.6)	42 (100)	0.328
Number of intubation attempts (%)			< 0.001
1	16 (38.1)	37 (88.1)	
2	7 (16.7)	5 (11.9)	
3	18 (42.9)	–	
Cormack & Lehane grade			< 0.001
1	–	29 (69.0)	
2	13 (30.9)	11 (26.2)	
3	22 (52.4)	2 (4.8)	
4	7 (16.7)	–	
Ease of use (0–10; VAS score)	5 (4–7)	1 (0–3)	< 0.001

IQR — Interquartile Range; NS — not statistically significant

($p = 0.081$). Intubation with VieScope® compared with Macintosh laryngoscope involved better glottis visibility according to the Cormack and Lehane scale ($p < 0.001$); it also turned out easier ($p < 0.001$).

Manual cervical inline stabilization

In the manual cervical inline stabilization scenario, the duration of intubation when one attempt was needed equaled 30 s (24–34) when using VieScope® and 49 s (39–52) with Macintosh laryngoscope; the difference was statistically significant ($p < 0.001$; Tab. 2). The overall intubation time needed for successful intubation with VieScope® and Macintosh laryngoscope varied and amounted to 30.5 s (24–35) vs. 88 s (51–114) ($p < 0.001$). The success rate of first intubation attempt was 88.1% with VieScope® and 38.1% with Macintosh ($p < 0.001$). In turn, the total efficacy of intubation was close to 100% vs. 97.6% ($p = 0.328$). Intubation with VieScope® was characterized by statistically significantly better intubation parameters compared with Macintosh laryngoscope ($p < 0.001$) in terms of both glottis visibility and ease of the procedure.

DISCUSSION

The aim of the study was to evaluate difficult intubation performance among paramedics using standard Macintosh laryngoscope and VieScope® laryngoscope. To our knowledge, this is the first comparison of VieScope® laryngoscope with a direct laryngoscope in adult difficult airway conditions.

As the scientific literature lacks reports on the VieScope® laryngoscope, which would enable discussion of the results, the authors decided to relate the obtained data to articles on channeled laryngoscopes, which include VieScope®.

In the conducted simulation study, intubation with the new VieScope® laryngoscope was associated with higher efficiency of the first intubation attempt and shorter procedure duration for both tongue edema and manual cervical inline stabilization. Rognås et al. [9] showed that multiple endotracheal intubation attempts were associated with an increased overall incidence of complications, such as bleeding or pharyngeal edema, and might lead to a situation referred to as “cannot intubate, cannot ventilate” [12, 13].

As indicated by Driver et al. [14], the effectiveness of emergency intubation among difficult airway patients is insufficient and equals only 82% when an endotracheal stylet is used. Moreover, hypoxemia was observed in 14% of patients during intubation. In a tongue edema simulation study, Szarpak et al. [15] reported a 63.6% effectiveness of first intubation attempt with Macintosh laryngoscope.

Research indicates that alternative types of laryngoscopes, including channeled laryngoscopes, can be used instead of direct laryngoscopes, as they guarantee better glottis visibility in difficult airways. The above thesis has also been confirmed by the results obtained in the present study, where the efficacy of the first VieScope® endotracheal intubation attempt for tongue edema was 95.2% and turned out statistically significantly higher than that for Macintosh

laryngoscope (64.3%; $p < 0.001$). Szalast et al. [16] also emphasize the advantage of channeled laryngoscopes over direct laryngoscopes in difficult airways intubation: the efficacy of the first attempt intubation equaled 70.4% for Airtraq and 14.8% for Macintosh laryngoscope. The lower efficacy of intubation with both devices compared with our outcomes may result from the fact that in the Szalast et al. study, intubation was performed by a nurse and our study involved paramedics, who learn how to protect the airways with, among others, Macintosh or Miller laryngoscopes. In turn, Al-Ghamdi [17] indicate that Airtraq requires longer intubation times but less frequently causes sore throat compared with Macintosh when used by anesthesiologists with limited experience in patients with normal airways.

Endotracheal intubation under trauma conditions or suspicion of cervical spine injury in pre-hospital settings requires cervical spine stabilization with at least manual cervical inline stabilization. Numerous studies have shown that direct laryngoscopic intubation under such conditions is ineffective and prolonged in time compared with normal airway intubation [17–19]. In patients undergoing endotracheal intubation with cervical immobilization, Hosali et al. [20] showed that channeled laryngoscopes were superior to Macintosh laryngoscopes, with greater ease of intubation and lower impact on hemodynamic variables. In turn, as reported by Çolak et al. [21], a minimal cervical motion was obtained during tracheal intubation with the use of Airtraq types of laryngoscope compared with the Macintosh laryngoscope. The advantage of channeled laryngoscopes over Macintosh devices in terms of less movement of the cervical spine was also indicated by Hirabayashi et al. [22]. A meta-analysis conducted by Suppan et al. [23] relating to cervical spine immobilization intubation revealed that the Airtraq device reduced the risk of intubation failure when compared with Macintosh laryngoscope.

Another important aspect, besides the efficacy of intubation itself, is the duration of the procedure, directly related to the risk of hypoxia and thus of hypoxia-induced changes in the central nervous system. In the tongue edema and manual cervical inline stabilization scenarios, Vie Scope® intubation was significantly shorter than the procedure with Macintosh laryngoscope (30.5 s vs. 55 s and 30.5 s vs. 88 s, respectively). In pre-hospital conditions, the long duration of intubation also poses additional

problems, i.e. limited strength during rescue procedures; the intubating paramedic is excluded for more than 1 min from performing other procedures. In this case, it is necessary to make specific therapeutic choices. In a Szalast et al. study [16], intubation with Airtraq was significantly shorter than that with Macintosh (26 vs. 53 s, respectively). Rendeki et al. [24] indicated that Airtraq was superior to the Macintosh laryngoscope in difficult airway intubation performed by novice users. This finding is in line with studies by other researchers [25, 26].

Limitations and strengths

Owing to its specificity, the study has its strengths and weaknesses. The limitations may include, first of all, the conditions of medical simulation; however, this procedure was deliberate and dictated by the randomized, cross-over study design. Medical simulation is now a rapidly growing branch of medical science and allows for full standardization of the conditions of procedures without potential damage to a patient's health [27, 28]. Another limitation is the inclusion of paramedics; nevertheless, this professional group, acting under pre-hospital conditions, relatively often has to protect the patient's airways and can only count on their knowledge and skills [29]. Therefore, it is justified to search for intubation methods which will increase the effectiveness of this procedure when performed by paramedics under pre-hospital conditions. Currently, studies are planned to extend the research group to other medical professions.

The strengths of the study include its randomized, cross-over character, which was intended to minimize the learning curve effect. Also, we used the most modern simulators of an adult patient, as well as performed the first evaluation of a new type of laryngoscope. Another strong point of the study is the blinding of results at the stage of statistical analysis.

CONCLUSIONS

In this simulation trial, we found that VieScope® could be successfully used for intubation in difficult airways by paramedics with little simulation experience with this device. VieScope® was associated with shorter time and higher success rates of intubation attempt compared with Macintosh. The presented study is the first to report that VieScope® shows promise for further clinical evaluation.

Conflict of interest

The authors declare no conflict of interest.

Acknowledgements

The study was supported by the ERC Research Net and by the Polish Society of Disaster Medicine.

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Novel airway device Vie Scope in several pediatric airway scenario

A randomized simulation pilot trial

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Abstract

Context: Endotracheal intubation of pediatric patients is challenging, especially in the pre-hospital emergency setting and if performed by less experienced providers. Securing an airway should be achieved with a single intubation attempt, as each intubation attempt contributes to morbidity and mortality. A new airway device, the VieScope, was recently introduced into clinical market, but efficacy to reduced intubation attempts remains unclear thus far.

Objective: We aimed to compare endotracheal intubation by paramedics using the Vie Scope in different pediatric airway simulation conditions.

Methods: We conducted a randomized, cross-over simulation study. Following a theoretical and practical training session, paramedics performed endotracheal intubation in 3 different pediatric emergency scenarios: normal airway; tongue edema; cardiopulmonary resuscitation using the VieScope. Overall intubation success rate was the primary outcome. Secondary outcomes included number of intubation attempts, time to intubation, Cormack-Lehane grade, POGO score, and ease of use (using 1–100 scale).

Results: Fifty-five paramedics with at least 2 years of clinical experience and without any previous experience with the VieScope participated in this study. The overall intubation success rate was 100% in all 3 scenarios. The median intubation time was 27 (24–34) versus 27 (25–37) versus 29 (25–40) s for scenarios A, B, and C, respectively. In scenario A, all paramedics performed successful intubation with 1 single intubation attempt, whereas 2% of the paramedics had to perform 2 intubation attempts in scenario B and 9% in scenario C.

Conclusions: Results of this simulation study indicate preliminary evidence, that the VieScope enables adequate endotracheal intubation in the pediatric setting. Further clinical studies are needed to confirm these results.

Abbreviations: CONSORT = CONSolidated Standards of Reporting Trials, CPR = cardiopulmonary resuscitation, IRB = institutional review board, IQR = interquartile range, POGO = percentage of glottic opening, SD = standard deviation.

Keywords: airway management, pediatric, endotracheal intubation, medical simulation, paramedic

Editor: Abdelouahab Bellou.

This study was supported by the Polish Society of Disaster Medicine.

The authors report no conflicts of interest.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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How to cite this article: Maslanka M, Szarpak L, Ahuja S, Ruetzler K, Smereka J. Novel airway device Vie Scope in several pediatric airway scenario- a randomized simulation pilot trial. *Medicine* 2020;99:28(e21084).

Received: 20 March 2020 / Received in final form: 27 May 2020 / Accepted: 2 June 2020

<http://dx.doi.org/10.1097/MD.00000000000021084>

1. Introduction

Securing the airway is a fundamental skill in the treatment of critically ill or injured patients.^[1,2] Endotracheal intubation is widely considered the standard of care but requires high level of experience and regular re-training.^[3,4] The out-of-hospital emergency setting is even more challenging, especially if dealing with pediatric patients. Unanticipated difficulties during endotracheal intubation has been reported in up to 25% in pediatric and up to 10% in adult patients.^[3,5–7] Difficulties during endotracheal intubation is critical, as prolonged and/ or multiple intubation attempts are clearly associated with potentially deleterious consequences like desaturation, bradycardia or even death.^[8,9]

Videolaryngoscopy was introduced into clinical practice to ultimately ease endotracheal intubation more than a decade ago. Videolaryngoscopy is considered an acceptable alternate technique compared to direct laryngoscopy, but clinical evidence is mostly based on clinical studies performed in adult patients.^[10–12] Results of studies performed in adults cannot extrapolate into the pediatric population, as pediatric patients are much more challenging due to their more challenging airway anatomy and physiology.^[13,14] Videolaryngoscopy in pediatric patients is generally believed to provide favorable airway visualization, but

it remains unclear whether better visualization reduces intubation failures or reduces time to intubation.^[15,16]

Airway management in the pediatric out-of-hospital emergency setting is challenging, especially if performed by relatively unexperienced airway providers like paramedics.^[4,10,17] Airway assistance tools like bougies have been reported to be beneficial, especially if used by paramedics.^[18] Once the bougie is placed between the vocal cord, an endotracheal tube can be inserted via the bougie into the trachea. Although placement of the bougie is considered easier than endotracheal intubation, it is still sometimes challenging, mostly due to limited airway visualization. A newly developed airway device, called VieScope (Adroit Surgery, Oklahoma City, OK), was introduced into clinical market to combine the advantages of better airway visualization and introducing a bougie into the patient’s airway. The VieScope is a self-contained, battery powered, disposable scope. The VieScope takes advantage of a closed circular tube with a beveled end to visualize the vocal cords. Light is transmitted through the side wall of the tube from end to end as well as within the lumen. Hereby, visualization of the target tissue should be optimized by reducing the chance of light obstruction by secretions or blood. Endotracheal intubation by the VieScope involves a 2-step process. First, the device is inserted orally and visualizing of glottis through the clear cylindrical lumen of the intubation channel is obtained. Second, a bougie is inserted into patient’s trachea and the VieScope removed. Afterwards, a conventional endotracheal tube is railroaded over the bougie. Once the endotracheal tube is placed, the bougie is removed.

The aim of this study was to identify potential advantages of using the VieScope for intubation of pediatric patients. Specifically, we tested the clinical efficacy of the VieScope for endotracheal intubation during 3 different airway scenarios in a pediatric manikin setting.

2. Methods

This study was designed as a randomized, cross-over simulation study. This manuscript reports in accordance with the CONSolidated Standards of Reporting Trials (CONSORT) statement.^[19] The study protocol was approved by the Institutional Review Board of the Polish Society of Disaster Medicine (Approval no.: 21.08.2019.IRB). Paramedics with at least 2 years of experience in the out-of-hospital emergency setting were invited to participate in this study. Paramedics with less experience or any previous training in the VieScope were excluded. Written voluntary informed consent was obtained from each paramedic before the study.

2.1. Study design

All paramedics completed a brief questionnaire consisting of demographic information and prior clinical experience with any kind of laryngoscopes including VieScope (Table 1). All paramedics attended a 30-minute lasting lecture, covering basic principles of endotracheal intubation of pediatric patients and the modified intubation technique using the VieScope laryngoscope (Fig. 1).

After the lecture, all paramedics had a 10-minute practice period to familiarize themselves with the VieScope and perform endotracheal intubation on the Laerdal Airway Management Trainer (Laerdal, Stavanger, Norway). Once the training was completed, paramedics were guided to a separate testing area.

Table 1	
Baseline characteristics.	
Characteristics	Data (n = 55)
Sex, male, n (%)	42
Age	31 ± 5 y
Height	178 ± 5 cm
Weight	74 ± 9 kg
Intubation experience, n (%)	
Adult patients:	
Direct laryngoscope	55 (100%)
Videolaryngoscope	0 (0%)
Vie Scope	0 (0%)
Pediatric patients:	
Direct laryngoscope	12 (21.8%)
Videolaryngoscope	0 (0%)
Vie Scope	0 (0%)

The Pediatric HAL S3005 Advanced Simulator (Gaumard, Miami, FL), representing a 5-year-old child, was used to simulate the pediatric patient. The simulator was placed on a flat floor in neutral position. Paramedics were asked to perform endotracheal intubation using the VieScope in 3 separate airway scenarios in a randomized sequence using the Research Randomizer program (Fig. 2):

- Scenario A—Normal airway scenario.
- Scenario B—Tongue edema: The tongue edema was simulated by inflating the tongue using the simulator’s software.
- Scenario C—Cardiopulmonary resuscitation (CPR): endotracheal intubation was performed during ongoing external chest compression. To standardize the chest compressions, the mechanical chest compression system LUCAS3 was used (Stryker, Richmond, VA).

Once intubation was achieved, an anesthesia bag (producer) was connected with the endotracheal tube and a breath was given.



Figure 1. Vie Scope laryngoscope.

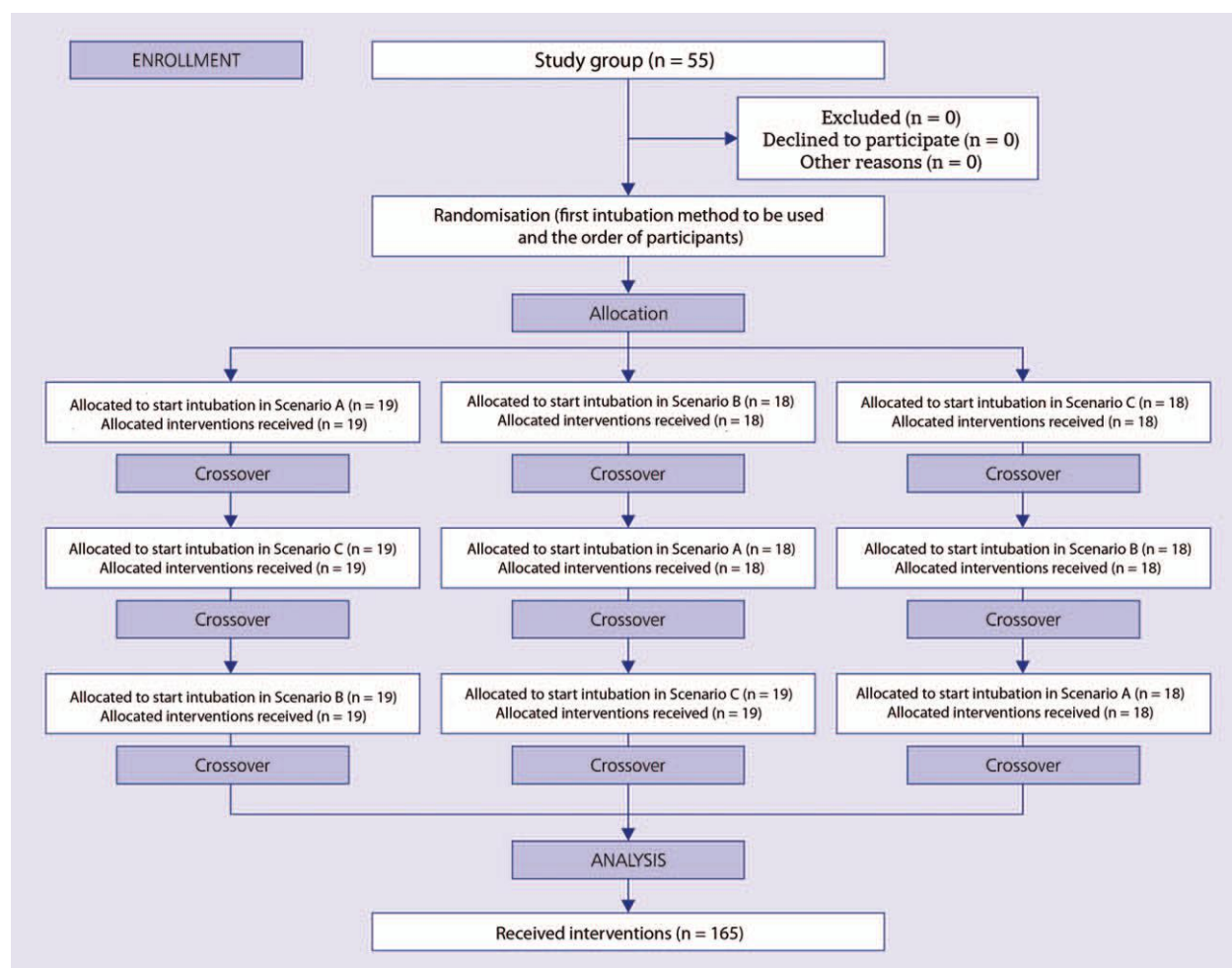


Figure 2. Randomization flow chart.

In adult patients, a bougie size 15Fr is primarily used with VieScope. For this study, the guide was replaced by a smaller diameter (mean 3.3 mm–10CH) guide adapted to the pediatric size of the endotracheal intubation tubes.

Each airway scenario was limited to a maximum of 60 seconds up to 3 intubation attempts. Between each airway scenarios, paramedics were having a break lasting for 20 minutes.

2.2. Measurements

The primary endpoint of the study was success rate of intubation. Successful intubation was confirmed by adequate ventilation of the lungs using the manikin software.

Time to intubation, defined as the time between insertion of the VieScope between the teeth until successful manual ventilation of the manikin's lungs, and number of intubation attempts served as the secondary outcomes. Additionally, after each attempt, paramedics were asked to rate airway visualization according to the Cormack-Lehane classification and the percentage of glottic opening (POGO) view.^[20] A 100% POGO score indicates visualization of entire glottis from the anterior commissure to the interarytenoid notch. A POGO score of 0 indicates that the interarytenoid notch cannot be visualized. Ease of use was

assessed with a visual analogue scale score ranging 1 to 100, where 1 meant "extremely easy" and 100 stood for "extremely difficult."

2.3. Statistical analysis

Sample size was calculated with G*Power 3.1 using a 2-tailed *t* test. A minimum of 39 paramedics were necessary to achieve a Cohen *d*=0.8, alpha error=0.05, power=0.95. To compensate for potential dropouts, we decided to enroll up to 55 paramedics into this study.

All statistical analyses were performed with the use of the Statistica 13.3 EN for Windows software (Tibco Inc.; Tulsa, OK). Data are presented as number (percentage), mean $\pm$ standard deviation (SD), or median (interquartile range [IQR]), as appropriate. Nonparametric tests were used for the data that did not have a normal distribution, which was tested with the Lilliefors test and the Shapiro–Wilk test. All statistical tests were 2-sided. The 1-way analysis of variance on ranks was applied to compare the different times and to determine the statistical difference for each group (post-hoc Bonferroni correction was used to counteract the problem of multiple comparisons). *P* value of <.05 was assumed statistically significant.

Table 2**Intubation parameters.**

Parameter	Scenario A	Scenario B	Scenario C
Success of intubation attempts (%)			
1 st	55 (100%)	54 (98%)	50 (91%)
2 nd	—	1 (2%)	5 (9%)
3 rd	—	—	—
Overall intubation success rate (%)	55 (100%)	55 (100%)	55 (100%)
Time to endotracheal intubation [s]	27 (24–34)	27 (25–37)	29 (25–40)
Cormack & Lehane grade			
1	42 (76%)	34 (62%)	39 (71%)
2	13 (24%)	21 (38%)	16 (29%)
3	—	—	—
4	—	—	—
POGO score, 1–100	95 (85–100)	85 (75–90)	85 (74–90)
Ease of use, 1–100	30 (20–35)	30 (28–40)	35 (30–43)

3. Results

Fifty-five paramedics participated in this study. Demographics and previous intubation experience are reported in Table 1. None of the paramedics had any previous training with the VieScope. Results are presented in Table 2.

In scenario A, all paramedics were able to intubate with the first intubation attempt. Two percent of the paramedics required a second intubation attempt in scenario B and 9% in scenario C. Overall success rate was 100% in all 3 airway scenarios.

The median time to intubation was 27 seconds (24–34 seconds) in scenario A, 27 seconds (25–37 seconds) in scenario B, and 29 (25–40 seconds) in scenario C.

4. Discussion

Our study revealed novel and promising findings for the new airway device VieScope. First, we report consistent 100% overall first pass intubation success rate by all paramedics, even in difficult airway scenarios. Second, the time to achieve intubation was almost similar in all 3 scenarios. Third, the data confirms reasonably well laryngeal visualization by VieScope as determined by Cormack and Lehane score and POGO score.

Time to secure the airway is crucial in the emergency setting. Pediatric advance life support recommendations suggest that total intubation time should not exceed 30 seconds.^[21] In our analysis, all paramedics achieved relatively quicker successful intubation (averaged 27–29 seconds) with the VieScope. In contrast, previous publications in the pediatric difficult airway manikin setting suggest prolonged intubation time exceeding the 30 seconds time limit using Miller and Macintosh laryngoscopes. Scenarios such as ongoing chest compressions during CPR increase time to intubation even more.^[22–25] The mean intubation time with VieScope during chest compressions was noted to be 29 seconds—interestingly, similar to normal airways scenario.

Previous studies investigating several videolaryngoscopes including the McGrath and the Trueview demonstrated relatively shorter time to intubation during CPR.^[26,27] This relatively longer time to intubation for the VieScope is based on the technique, as the VieScope includes 2 separate steps—introducing the bougie between vocal cords and the endotracheal tube via the bougie into the trachea. However, our intubation times are broadly in keeping with a recent randomized clinical trial,

comparing intubation with bougie and endotracheal tube with stylet in adult emergency settings.^[28]

Multiple intubation attempts substantially increase risk of overall adverse events and leads to prolonged intubation.^[9,29] Previous work suggests that an additional intubation attempt in pediatrics population exponentially increases the risk of severe desaturation (below 80%).^[9,30] Notably, we found very few instances requiring another attempt. For example, second intubation attempt was noted in only 2% of the tongue edema scenario and only 9% in the CPR scenario. A similar study comparing Macintosh laryngoscope and McGrath videolaryngoscope during ongoing CPR demonstrated comparable first-time success rate (91% vs 98%) by paramedics.^[31] Importantly, our paramedics were not previously trained to use VieScope and achieved reassuring first pass success rate of >90%, in difficult scenarios.

We also analyzed laryngeal visualization as another outcome and found that VieScope provides better visualization and superior laryngoscopic view, as shown by better Cormack-Lehane classification and POGO score. Likewise, participants rated VieScope as relatively easy to intubate device, consistently in all 3 scenarios.

Endotracheal intubation using different kinds of bougies is a simple, inexpensive technique first described in 1949. This technique is mostly reserved primarily for patients with poor laryngeal views or as a rescue device, if initial intubation attempt failed.^[32] In adult patients, several studies in a wide range of different settings indicate a higher intubation success rate and lower intubation-related adverse events.^[28,29,33,34] Intubation success rate with a bougie is reported to be up to 96% in the emergency setting, if performed by physicians.^[28]

Our analysis has several limitations. First, it is worth noting that our study is a preliminary manikin study, the results of which are often difficult to extrapolate to the general human population. However, we tried to simulate the clinical practice scenario as closely as possible with strict standardization, but they can never fully translate actual clinical scenarios. Second, to provide more reliable evaluation and reduce bias, we recruited paramedics who had previous experience with direct laryngoscopy, but the results may be different in novice hands. Furthermore, no comparisons were made with other devices and the manikin morphological anatomy may favor a specific airway device which may distort the results. Lastly, our manikin study design did not allow us to evaluate VieScope and its bougie-related complications such as airway trauma, although bougies are generally considered safe devices.^[35,36]

5. Conclusions

Based on preliminary manikin study, our results emphasized that VieScope may be helpful to achieve quicker, favorable first pass success rate in normal and difficult airways scenarios, with minimum learning curve. It appears that VieScope may be a useful addition to already available airway devices for difficult airway scenarios. However, future comparative manikin and clinical studies will be needed to ascertain the advantages of VieScope over another airway device while including the clinical as well as practical aspects in prehospital settings.

Author contributions

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Contents lists available at ScienceDirect

American Journal of Emergency Medicine

journal homepage: www.elsevier.com/locate/ajem

Vie scope® laryngoscope versus Macintosh laryngoscope with personal protective equipment during intubation of COVID-19 resuscitation patient

Dear Editor,

Airway management is a key element of resuscitation procedures. However, due to the current COVID-19 pandemic, medical personnel should complete medical procedures wearing full personal protective equipment (PPE) for aerosol-generating procedures (AGP) [1]. PPE-AGP should be used especially during cardiopulmonary resuscitation, including airway management [2]. Emergency intubation using direct laryngoscopy carries a significant risk of failure. As many authors indicate, the effectiveness of the first intubation attempt with a Macintosh laryngoscope is from 57.6% to 89.9% [3,4]. The use of PPE-AGP may reduce the efficiency of medical procedures and prolong their duration [5,6]. Intubation methods alternative to Macintosh laryngoscope may be a suitable solution. An example of a new type of laryngoscope is Vie Scope® (Adroit Surgical, Oklahoma City, USA), which is a self-contained, battery-powered, disposable scope that takes advantage of a closed circular tube with a beveled end to visualize the vocal cords (Fig. 1). The light is transmitted through the sidewall of the tube from end to end as well as within the lumen of the tube. The intubation procedure using Vie Scope® should be based on the following steps – the intubator should: (1) insert scope and identify glottis opening between vocal cords, (2) pass the bougie under direct vision between the vocal cords into the trachea, (3) remove the scope leave the bougie in place, (4) pass the endotracheal tube over the bougie into the trachea, (5) remove the bougie, (6) ventilate.

The aim of this study was to evaluate intubation performance by paramedics wearing PPE-AGP using Macintosh laryngoscope and Vie Scope® laryngoscope under simulated resuscitation of COVID-19 patient.

The study was designed as a prospective randomized crossover simulation trial. The study protocol was approved by the Institutional Review Board of the Polish Society of Disaster Medicine (No. 15.11.2019. IRB). 42 working paramedics took part in the study. Voluntary informed consent was obtained from each participant. None of the participants had previous experience with the Vie Scope® laryngoscope. Before the examination, the participants took part in the presentation of the laryngoscope and the method of correct intubation using it. The study participants then attended a 20-minute practical training course during which they performed endotracheal intubation using Vie Scope® under normal airway conditions. During the target study, paramedics dressed in full PPE-AGP were to perform endotracheal intubation with continuous chest compression. Endotracheal intubation was performed using Macintosh laryngoscope (MAC; blade no.3) as well as with Vie

Scope® laryngoscope (VSC). The advanced SimMan 3G adult patient simulator (Stavanger, Norway) was used to simulate a patient requiring endotracheal intubation. A standard intubation guide was used for MAC and a bougie guide for VSC. Each participant had a maximum of 3 attempts to intubate using each device. Both the order of participants and intubation methods were random. A detailed randomization procedure is presented in Supplementary Fig. 1. The data were blinded for the team interpreting the results. The results were analyzed using the statistical package STATISTICA 13.3EN (Tibco Inc., USA) or Review Manager 5.4EN (Cochrane Collaboration, Oxford, UK). Group differences in dichotomous data are expressed as odds ratios (ORs) and group differences in continuous data as mean differences (MDs), both with 95% confidence intervals (CIs). The fixed-effect model was used to pool the results.

Duration of intubation when one attempt needed between distinct intubation methods varied and amounted to 44 (IQR; 40.5–53)sec. For MAC and 28.5 (IQR; 25–38.5)sec. For VSC (MD = 15.30; 95%CI: 13.69, 16.91; $p < 0.001$). Median overall intubation time with MAC was 47 s (IQR; 41.5–95.5) and was statistically significantly longer than with VSC – 29 s. (IQR; 25–39; MD = 27.30; 95%CI: 22.43, 32.17; $p < 0.001$). First attempt success rate with MAC was 50.0% vs. 92.9% for VSC (MD = 0.08; 95%CI: 0.02, 0.29; $p < 0.001$), and overall success rate was 90.5 vs. 100% respectively (MD = 0.10; 95%CI: 0.01, 1.93; $p = 0.13$). The ease of intubation is based on the VAS scale (0 – „easy procedure” to „10” – difficult procedure) varied and amounted to 5 (IQR, 4–8) vs. 2 (IQR; 2–5) points (MD = 2.75; 95%CI: 2.34, 3.16; $p < 0.001$).

In conclusion, under the conditions of intubation performed by paramedics wearing PPE-AGP with continuous chest compression, the results of the study indicate higher efficiency of intubation with Vie Scope® compared to Macintosh laryngoscope in terms of both the efficiency of the first intubation attempt and the time of the procedure. Further studies are required to confirm the results.

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ajem.2020.08.085>.

Declaration of Competing Interest

None.

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Fig. 1. Intubation using Vie Scope laryngoscope

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8 July 2020

Available online xxxx

4. PODSUMOWANIE I WNIOSKI

Przedstawiona rozprawa doktorska składa się z cyklu czterech badań. Trzy spośród tych badań dotyczą porównania nowego laryngoskopu Vie Scope® ze standardowym laryngoskopem z łopatką Macintosha w różnych warunkach intubacyjnych [32,33,34]. Z kolei czwarta praca to meta-analiza stanowiąca porównanie intubacji z wykorzystaniem kanałowego laryngoskopu AirTraQ z laryngoskopem Macintosha [35]. Spośród badań wchodzących w skład monotematycznego cyklu publikacji, trzy prace to prace pełnotekstowe [32,33,35], zaś jedna to list do redakcji o charakterze badawczym [34].

Pierwsze badanie zaprojektowane jako przegląd systematyczny i meta-analiza odnosiło się do porównania efektywności intubacji z wykorzystaniem laryngoskopu AirTraQ oraz laryngoskopu z łopatką Macintosha [35]. Stanowi ono swoisty wstęp do poruszanego w dysertacji tematu intubacji dotchawiczej z wykorzystaniem Vie Scope®. Z uwagi na brak badań dotyczących tego typu laryngoskopu, postanowiono przeprowadzić analizę efektywności laryngoskopu AirTraQ, który jest najczęściej stosowanym laryngoskopem kanałowym na świecie [35].

Celem drugiej pracy było porównanie efektywności intubacji dotchawiczej laryngoskopem Vie Scope®. Jako złoty standard intubacji zastosowano laryngoskop z łopatką Macintosha [33]. W pracy udział wzięło 42 ratowników medycznych którzy mieli za zadanie wykonanie intubacji dotchawiczej w dwóch scenariuszach badawczych: a) scenariusz obrzęku języka; b) scenariusz ręczna stabilizacja odcinka szyjnego kręgosłupa.

Celem trzeciej pracy była ocena skuteczności intubacji pacjenta pediatrycznego z wykorzystaniem laryngoskopu Vie Scope®. W badaniu udział wzięło 42 ratowników medycznych, którzy posiadali minimum dwa lata doświadczenia w warunkach zespołów wyjazdowych ratownictwa medycznego. Uczestnicy badania mieli za zadanie wykonanie intubacji w sposób randomizowany krzyżowy w trzech następujących scenariuszach badawczych: a) normalne drogi oddechowe; b) obrzęk języka; c) ciągła kompresja klatki piersiowej podczas symulowanej resuscytacji krążeniowo – oddechowej [32].

W badaniu czwartym, którego celem było porównanie intubacji z wykorzystaniem laryngoskopu Vie Scope® i laryngoskopu z łopatką Macintosha udział wzięło również 42 ratowników medycznych. Badanie to było badaniem pionierskim w zakresie wykorzystania

laryngoskopu Vie Scope® w warunkach intubacji pacjenta z podejrzeniem choroby zakaźnej. Podczas badania personel medyczny był ubrany w kombinezony ochrony osobistej chroniące przeciwko aerozolom zakaźnym [34].

Umiejętność efektywnego zabezpieczenia drożności dróg oddechowych stanowi jedną z podstawowych procedur jakie powinien umieć wykonywać personel medyczny – w szczególności personel zespołów ratownictwa medycznego. Zastosowanie intubacji dotchawiczej nadal stanowi „złoty standard” zabezpieczenia dróg oddechowych, w tym podczas działań ratunkowych [4,36]. Intubacja dotchawicza pozwala na pełną izolację dróg oddechowych pacjenta, co ma kluczowe znaczenie w aspekcie pacjentów zakaźnych. Ponadto w przypadku resuscytacji krążeniowo – oddechowej pozwala na prowadzenie asynchronicznej resuscytacji, która jak wskazują liczne publikacje jest najbardziej efektywną formą kompresji klatki piersiowej [37,38].

W badaniu pierwszym podjęto próbę oceny wykazano wyższą skuteczność intubacji z wykorzystaniem AirTraq w porównaniu z laryngoskopem z łożatką Macintosha [odpowiednio: 85,6% i 68,4%; OR = 3,00; 95%CI: 1,37, 6,60]. Zastosowanie AirTraq związane było również z nieznacznie krótszym czasem trwania procedury intubacji w porównaniu do laryngoskopu z łożatką Macintosha [MD = -3,19; 95%CI: -9,33, 2,95]. Z kolei Hoshijima i wsp. w swojej meta-analizie oceniającej intubację w warunkach bloku operacyjnego i oddziału intensywnej terapii wskazują na przewagę wideolaryngoskopu McGrath w porównaniu do laryngoskopu z łożatką Macintosha wskazują na przewagę wideolaryngoskopu McGrath w aspekcie uwidocznienia głośni. Jednakże wskazują na dłuższy czas intubacji w przypadku wideolaryngoskopii. W przypadku intubacji dotchawiczej wykonywanej przez specjalistów anestezjologii i intensywnej terapii wideolaryngoscopia może wiązać się z wydłużeniem czasu trwania procedury, co jest podyktowane wysokimi umiejętnościami praktycznymi a zarazem doświadczeniem w zakresie laryngoskopii bezpośredniej. Jednakże w aspekcie pacjentów z trudnymi drogami oddechowymi, w tym także pacjentów otyłych wideolaryngoscopia wykazuje znaczącą przewagę nad laryngoskopią bezpośrednią [39,40]. Liczne badania wskazują również przewagę wideolaryngoskopii nad standardowymi laryngoskopami w przypadku resuscytacji krążeniowo – oddechowej [41,42]. Zastosowanie tego typu urządzeń podczas intubacji może wpłynąć na zmniejszenie czasu niedotlenienia pacjenta a tym samym poprawić jego rokowanie. Wartym podkreślenia w tym miejscu jest również fakt, iż

intubacja dotchawicza w warunkach przedszpitalnych czy też Szpitalnego Oddziału Ratunkowego różni się znacznie od intubacji w warunkach bloku operacyjnego. W warunkach przedszpitalnych intubacja dotchawicza jest wykonywana ze względów ratujących życie, zaś w przypadku bloku operacyjnego jest to intubacja planowa, przed którą anestezjolog ma czas na premedykację pacjenta, preoksygenację oraz wykonanie procedury w komfortowych warunkach, w tym przy dobrym oświetleniu. Z kolei zaś intubacja w warunkach zespołów ratunkowych niejednokrotnie wykonywana jest pod presją czasu jak to ma miejsce np. podczas resuscytacji krążeniowo – oddechowej, jak również w niesprzyjających warunkach atmosferycznych czy też oświetleniowych. Stąd skuteczność intubacji dotchawiczej wykonywanej przedszpitalnie różni się od skuteczności intubacji podejmowanej przez specjalistów anestezjologii i intensywnej terapii w ramach przygotowania do zabiegu operacyjnego [43].

W badaniu drugim porównującym Vie Scope® oraz laryngoskop z łopatką Macintosa w aspekcie intubacji dotchawiczej osoby dorosłej wykazano przewagę Vie Scope® zarówno w przypadku intubacji w warunkach obrzęku języka jak również manualnej stabilizacji odcinka szyjnego kręgosłupa [33]. Przewagę Vie Scope® obserwowano zarówno w aspekcie skuteczności intubacji, stopnia uwidocznienia głośni, jak również czasu trwania samej procedury. Jak wskazują badania Gawłowskiego i wsp. [28,44] intubacja dotchawicza w przypadku urazu odcinka szyjnego kręgosłupa unieruchomionego za pomocą kołnierza szyjnego może być utrudniona. Wówczas zasadnym jest rozpięcie kołnierza i wykonanie manualnej stabilizacji głowy i odcinka szyjnego kręgosłupa na czas wykonania procedury zabezpieczenia drożności dróg oddechowych.

W badaniu odnoszącym się do oceny efektywności intubacji z wykorzystaniem laryngoskopu Vie Scope® przeprowadzono badanie symulacyjne w aspekcie intubacji pacjenta pediatrycznego [32]. Było to pierwsze badanie tego typu ewaluujące laryngoskop Vie Scope® w aspekcie intubacji dziecka. Pomimo iż Vie Scope® jest laryngoskopem dedykowanym dla osób dorosłych, jak wykazano w powyższym badaniu skuteczność pierwszej próby intubacji wynosiła powyżej 90% niezależnie od scenariusza badawczego (normalne drogi oddechowe, obrzęk języka, ciągła kompresja klatki piersiowej). Wyniki wskazują zatem na możliwość utylitarnego zastosowania laryngoskopu Vie Scope®. Uzyskane wyniki są tym bardziej istotne, gdyż jak wskazują badania Yurtseven i wsp. skuteczność pierwszej próby intubacji pacjenta pediatrycznego w warunkach Szpitalnego

Oddziału Ratunkowego wynosi zaledwie 66% [9]. Na niską skuteczność pierwszej próby intubacji pacjenta pediatrycznego w oparciu o laryngoskopię bezpośrednią wskazują również inni autorzy [45,46].

W dobie panującej pandemii COVID-19 szybkie zabezpieczenie dróg oddechowych ma kluczowe znaczenie, zwłaszcza w aspekcie resuscytacji krążeniowo – oddechowej. Jak wskazują liczne badania, intubacja dotchawicza stanowi jedną z procedur, które mogą generować aerozol zakaźny, co w przypadku pacjentów zakażonych koronawirusem SARS-CoV-2 jest niezwykle niebezpieczne zarówno dla świadków zdarzenia a w szczególności personelu medycznego wykonującego medyczne czynności ratunkowe [47,48]. W związku z powyższym zasadnym jest stosowanie przez personel medyczny środków ochrony osobiste w postaci pełnych kombinezonów ochronnych. Jednakże taka forma zabezpieczenia ratownika medycznego, pielęgniarki czy też lekarza, gdy jest on ubrany w pełny kombinezon ochronny, maskę twarzową, gogle, przyłbicę i podwójne rękawiczki może redukować efektywność procedur medycznych, poczynając od kompresji klatki piersiowej, poprzez uzyskiwanie dostępów donaczyniowych a na intubacji dotchawiczej kończąc. Taylor i wsp. [49] wskazują na istotne zmniejszenie skuteczności pierwszej próby intubacji dotchawiczej w przypadku stosowania kombinezonów ochronnych w porównaniu z intubacją w normalnych warunkach (58% i 96%, $P < 0,001$). Ponadto wykonywanie intubacji w kombinezonie ochronnym w badaniu Taylor wiązało się z dłuższym czasem wykonania procedury (odpowiednio, 35,0s i 22,2s, $P = 0,012$).

W związku z trudnościami bądź całkowitą niemożliwością osłuchiwania pacjenta w przypadku stosowania kombinezonów ochronnych, personel medyczny powinien stosować kapnografię bądź ultrasonograficzne jako metodę potwierdzenia poprawności wprowadzenia rurki intubacyjnej [50,51]. Kapnografia w aspekcie pacjentów z zatrzymaniem krążenia ma jeszcze dodatkowy aspekt – pozwala na weryfikację jakości kompresji klatki piersiowej [52,53].

Jak wskazują Szarpak i wsp. wartym rozważenia w przypadku intubacji dotchawiczej pacjenta z podejrzeniem COVID-19 jest zastosowanie wideolaryngoskopów [50]. Również Arulkumaran i wsp. [54] wskazują na przewagę wideolaryngoskopii nad laryngoskopią bezpośrednią zarówno w aspekcie redukcji ryzyka wprowadzenia rurki intubacyjnej do przełyku [OR = 0,32; 95%CI: 0,14, 0,70], redukcji urazów [OR = 0,74; 95%CI: 0,34, 1,62] jak również redukcji ryzyka odruchowej hipotensji [OR = 1,49; 95%CI: 1,00, 2,23]. Również

Schumacher również wskazuje na skrócenie czasu intubacji przy zastosowaniu wideolaryngoskopii w przypadku stosowania kombinezonu ochrony osobistej [55,56]. Z kolei Claret i wsp. w randomizowanym krzyżowym badaniu symulacyjnym wykazali, iż personel SOR był w stanie z wyższą skutecznością intubacja z wykorzystaniem laryngoskopu z łożatką Macintosha aniżeli laryngoskopem AirTraq [57]. Jednakże w rzeczonym artykule intubacja odbywała się w warunkach normalnych dróg oddechowych. Z uwagi na wytrenowanie personelu medycznego w zakresie laryngoskopii bezpośredniej, wideolaryngoscopia wykazuje znaczącą przewagę w warunkach trudnych dróg oddechowych bądź w przypadku intubacji przez personel posiadający mniejsze doświadczenie w zakresie intubacji z wykorzystaniem laryngoskopów z łożatkami Macintosha bądź Millera [4,58,59]. Jednakże warto zaznaczyć, iż w warunkach przedszpitalnych z uwagi na wysoką cenę wideolaryngoskopów są one rzadkością. W związku z powyższym kluczowe jest poszukiwanie alternatywnych dla laryngoskopii bezpośredniej technik intubacji dotchawiczej, które będą wykazywały się wyższą efektywnością i nie będą generowały dużego obciążenia finansowego dla dysponentów systemu Państwowego Ratownictwa Medycznego. Przykładem tego typu rozwiązań może być laryngoskop Vie Scope®, który jest nowym na rynku medycznym laryngoskopem jednorazowego użytku. W badaniu własnym, będącym jedynym badaniem ukazującym intubację dotchawiczą z wykorzystaniem Vie Scope® przez ratowników medycznych ubranych w kombinezony ochronne, wykazano statystycznie istotnie krótszy czas pierwszej próby intubacji z wykorzystaniem Vie Scope® aniżeli laryngoskopem z łożatką Macintosha [MD = 15,30; 95%CI: 13,69, 16,91] [34]. Ponadto intubacja z wykorzystaniem VieScope w porównaniu z laryngoskopią bezpośrednią wiązała się z wyższą skutecznością pierwszej próby intubacji [92,9% i 50,0%; MD = 0,08; 95%CI: 0,02, 0,29], całkowitej skuteczności [100% i 90,5%; MD = 0,10; 95%CI: 0,01, 1,93], jak również łatwości intubacji dotchawiczej [MD = 2,75; 95%CI: 2,34, 3,16].

Wszystkie cztery publikacje objęte tematem rozprawy doktorskiej są związane z oceną skuteczności ratunkowej intubacji dotchawiczej zarówno pacjentów dorosłych jak i pediatrycznych w różnych scenariuszach symulacyjnych.

Przeprowadzone badania pozwalają na sformułowanie następujących wniosków:

- AirTraq jako przykład laryngoskopu kanałowego stanowi alternatywę dla laryngoskopii bezpośredniej zwiększając skuteczność pierwszej próby intubacji, zwłaszcza w aspekcie unieruchomienia odcinka szyjnego kręgosłupa.
- Intubacja dotchawicza z wykorzystaniem Vie Scope® w porównaniu z laryngoskopem z łopatką Macintosha jest wykazuje wyższą efektywność w przypadku zabezpieczania dróg oddechowych pacjenta pediatrycznego.
- Vie Scope® w badaniu symulacyjnym wykazuje wysoką skuteczność pierwszej próby intubacji zarówno w aspekcie normalnych jak i trudnych dróg oddechowych.
- W przypadku intubacji pacjenta z podejrzeniem choroby zakaźnej, gdy personel medyczny ubrany jest w kombinezony ochronne zastosowanie laryngoskopu Vie Scope® znacząco skraca czas intubacji jak również zwiększa szanse na skuteczną intubację.

5. OŚWIADCZENIA AUTORÓW PUBLIKACJI

Dr hab. n. med. Jacek Smereka, Prof. UMW

.....
(imię i nazwisko)

Wrocław, 28.11.2020r.

.....
(miejscowość, data)

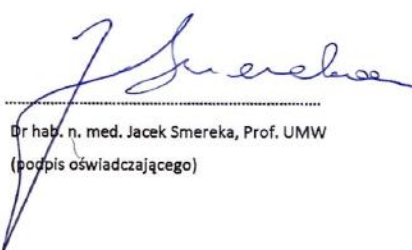
OŚWIADCZENIE

Jako współautor pracy:

Maciej Maślanka, Jacek Smereka, Michał Pruc, Oliver Robak, Kecskés Attila, Łukasz Szarpak, Kurt Ruetzler. Airtraq® versus Macintosh laryngoscope for airway management during general anesthesia: A systematic review and meta-analysis of randomized controlled trials. Disaster and Emergency Medicine Journal. 2020; 5(4) (praca przyjęta do druku)

oświadczam, iż mój własny wkład merytoryczny w przygotowanie, przeprowadzenie i opracowanie badań oraz przedstawienie pracy w formie publikacji stanowi: współudział w przeglądzie systematycznym literatury naukowej oraz przygotowaniu manuskryptu. Mój udział procentowy w przygotowaniu publikacji określám jako 5%.

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Warszawa, 28.11.2020r.

(miejscowość, data)

OŚWIADCZENIE

Jako współautor pracy:

Maciej Maślanka, Jacek Smereka, Michał Pruc, Oliver Robak, Kecskés Attila, Lukasz Szarpak, Kurt Ruetzler. Airtraq® versus Macintosh laryngoscope for airway management during general anesthesia: A systematic review and meta-analysis of randomized controlled trials. Disaster and Emergency Medicine Journal. 2020; 5(4) (praca przyjęta do druku)

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Wiena, 28 Nov 2020

(city, date)

OŚWIADCZENIE

As a co-author of manuscript:

Maciej Maślanka, Jacek Smereka, Michał Pruc, Oliver Robak, Kecskés Attila, Lukasz Szarpak, Kurt Ruetzler. Airtraq® versus Macintosh laryngoscope for airway management during general anesthesia: A systematic review and meta-analysis of randomized controlled trials. Disaster and Emergency Medicine Journal. 2020; 5(4) (manuscript accepted for publication)

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OŚWIADCZENIE

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Maciej Maślanka, Jacek Smereka, Michał Pręc, Oliver Robak, Kecskés Attila, Lukasz Szarpak, Kurt Ruetzler. Airtraq® versus Macintosh laryngoscope for airway management during general anesthesia: A systematic review and meta-analysis of randomized controlled trials. Disaster and Emergency Medicine Journal. 2020; 5(4) (manuscript accepted for publication)

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OŚWIADCZENIE

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OŚWIADCZENIE

As a co-author of manuscript:

Maciej Maślanka, Jacek Smereka, Michał Pruc, Oliver Robak, Kecskés Attila, Lukasz Szarpak, Kurt Ruetzler. Airtraq® versus Macintosh laryngoscope for airway management during general anesthesia: A systematic review and meta-analysis of randomized controlled trials. Disaster and Emergency Medicine Journal. 2020; 5(4) (manuscript accepted for publication)

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Wrocław, 28.11.2020r.

(miejscowość, data)

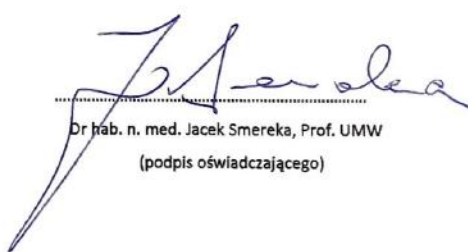
OŚWIADCZENIE

Jako współautor pracy:

Maciej Maślanka, Jacek Smereka, Lukasz Czyzewski, Jerzy Ladny, Marek Dabrowski, Lukasz Szarpak. VIESCOPE ® LARYNGOSCOPE VERSUS MACINTOSH LARYNGOSCOPE DURING DIFFICULT INTUBATION PERFORMED BY PARAMEDICS: A RANDOMIZED CROSSOVER MANIKIN TRIAL. Disaster and Emergency Medicine Journal 2020, Vol. 5, No. 3, 134–141; DOI: 10.5603/DEMJ.a2020.0031

oświadczam, iż mój własny wkład merytoryczny w przygotowanie, przeprowadzenie i opracowanie badań oraz przedstawienie pracy w formie publikacji stanowi: współudział w przeglądzie literatury oraz przygotowaniu manuskryptu. Mój udział procentowy w przygotowaniu publikacji określłam jako 5%.

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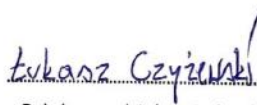
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Jako współautor pracy:

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(imię i nazwisko)

Białystok, 28.11.2020r.

(miejscowość, data)

OŚWIADCZENIE

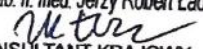
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Poznań, 28.11.2020r.

(miejscowość, data)

OŚWIADCZENIE

Jako współautor pracy:

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Warszawa, 28.11.2020r.

(miejscowość, data)

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I declare that my own substantive contribution to the preparation, conduct, and develop research and presentation of work in the form of publication is: drafting the manuscript for important intellectual content.

My percentage in the preparation of publication refer to as the 5%.

I also agree to use this manuscript as a part of a doctoral dissertation of Maciej Maślanka.



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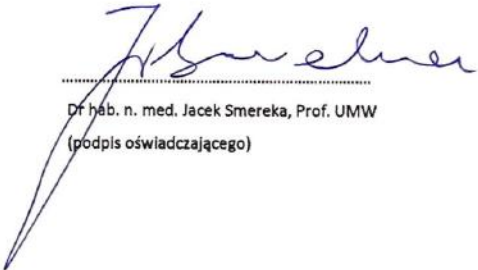
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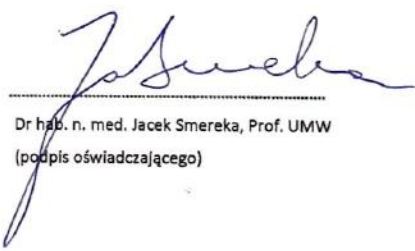
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6. SPIS RYCIN

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