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A Cross-Sectional Study Evaluating the GuardianCPV™ Supraglottic Airway Device in a Clinical Setting

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Abstract

Objective: The GuardianCPV™ is a new second-generation supraglottic airway device (SAD), for which there is currently limited information on efficacy or safety. Our aim is to clarify further the efficacy of the Guardian, and to assess any potential predictors for success or failure of insertion.

Methods: We conducted a cross-sectional pilot study over a two-month period, recruiting 67 operative cases (33 males; 34 females; weight 81.1 ± 23.0 kg) at the Northern Hospital (TNH), Victoria, Australia, that used the Guardian airway in an elective setting. For each case, the operator of the airway reported, via a voluntary questionnaire, several factors of interest: (1) the overall success rate (primary outcome); (2) ease of insertion; (3) cuff seal pressure (CSP); (4) need for repositioning of the SAD; and (5) patient, airway, operator and technique-related predictors, including past experience with the Guardian (as determined by number of times previously used) and insertion technique.

Results: The overall success rate was 78%. There was a positive association between prior experience with the Guardian and subsequent success rates ($p=0.049$). Successful insertion was associated with greater ease with insertion ($p=0.012$), and greater CSPs ($p<0.0001$). The most popular insertion technique was sideways-and-rotate. No other patient, airway or technique-related factors had any significant impact on success rates with the Guardian.

Conclusion: The Guardian SAD demonstrated similar efficacy to other SADs as reported in the literature. Prior familiarization with a new airway device is a key determinant in its successful use.

Keywords: Airway management; Laryngeal mask

Abbreviations: CSP: Cuff Seal Pressure; OLP: Oropharyngeal Leak Pressure; SAD: Supraglottic Airway Device; TNH: The Northern Hospital.

Background

The Guardian CPV™ ("Guardian") is a second-generation supraglottic airway device (SAD) developed in 2011 by Ultimate Medical (Richmond, Australia). There is currently limited information on the safety and efficacy of this particular model. Other popular second-generation SADs (LMA Supreme™, i-gel®, Proseal LMA™) typically achieve success rates of 71 to 100% [1-9]. At the time that this study was performed, there was only one known study in the literature that specifically assessed the Guardian, comparing it with the Supreme [10]. According to that study, efficacy was equivalent between both models, with equivalent insertion success rates on first attempt (100%), and slightly superior oropharyngeal leak pressure (OLP) for the Guardian compared to the Supreme.

The purpose of this study is to further characterize the efficacy of the Guardian in a tertiary hospital setting, and to identify factors that may contribute to its success or failure. We hypothesized that the success rate of insertion for the Guardian is comparable to those of other SADs reported in the literature.

Materials and Methods

Sample collection

We conducted a prospective pilot study of adult operative cases from the Northern Hospital (TNH), Epping, Australia, that used the Guardian, from 1st May 2013 to 31st July 2013. Anesthetists and medical trainees were approached and recruited for the study on a voluntary basis. For each case, the characteristics and outcomes were reported via a questionnaire (Table 1) by the individual who performed the SAD insertion (i.e. the "operator"). In all cases, the Guardian was used electively and not as rescue device. The study was approved by the Northern Health Human Research Ethics Committee via the low-risk pathway. All cases were de-identified prior to statistical analysis. The existing literature for the Guardian LMA reports 100% success rate. [10,11] Using G*Power [12], a sample size of at least 50 was needed to identify a statistically-significant difference (one-tailed, $\alpha=0.05$, $\beta=0.80$) from an expected success rate of 95% to an actual success rate of 80%.

Evaluation of outcomes

The primary outcome of interest was the rate of successful insertion for the Guardian. Success in this context was defined as the ability to ventilate through, and the continued use of, the Guardian airway without need for replacement with an alternative device, and regardless

of the number of attempts. Other outcomes assessed were the total number of insertion attempts; ease of insertion; cuff seal pressure (CSP); and need for physical repositioning of the SAD in the airway.

The ease of insertion was evaluated via an ordinal scale, from one to five in ascending order of difficulty (Table 1)-a score of one was equivalent to the device slipping in without effort; a score of three meant that the insertion required additional assistance from other theatre staff; and a score of five meant complete failure of insertion.

The cuff seal pressure (CSP) was defined as the maximum pressure that the anesthetist could apply via positive pressure ventilation, with the adjustable pressure limiting valve closed, before a leak was detected. The CSP was used as a surrogate measure for oropharyngeal leak pressure (OLP), due to limitations in the precise measurement of OLP in the acute theatre setting. Again, CSP was evaluated as an ordinal variable on a scale from one to five. A score of one denoted a pressure above 30 cmH_2O; a score of two for pressures from greater than 22.5 to 30 cmH_2O; a score of three for pressures from 15 to 22.5 cmH_2O; a score of four for pressures less than 15 cmH_2O but with achievable ventilation; and a score of five for cases where ventilation was not possible at all.

From the collated data we then estimated the proportion of all cases where "clinically-positive" outcomes were obtained. These positive outcomes were explicitly defined as follows: (1) number of insertion attempts was less than three; (2) the score for ease of insertion was less than three; (3) the CSP was greater than 15 cmH_2O (i.e. CSP score was less than four); and (4) no SAD repositioning was required.

Property	Options	Scoring
Patient-related		
Sex	Male Female	-
Weight, in kg	-	-
Airway-related		
Mallampati score	-	1 2 3 4
Thyromental score (and distance, in cm)	<6 cm	1
	6 to 8 cm	2
	>8 cm	3
Teeth	Full set	1
	Partial set	2
	Edentulous	3
SAD size	3	1
	4	2
	5	3
Operator-related		
Operator level	Resident/intern	1
	Registrar	2
	Consultant	3
Previous use of Guardian SAD	0 to 4	1
	5 to 10	2
	>10	3
Outcomes		
Ease of insertion score	Slips in with ease	1
	Slips in with difficulty, but able to manage on own	2
	Requiring some help from other staff	3
	Requiring significant help from other staff	4
	Unable to insert	5
Number of attempts at insertion	1	1
	2	2
	≥ 3	3
Degree of cuff inflation	Cuff fully deflated	1
	Cuff partially inflated	2
	Cuff fully inflated	3
Insertion technique	Pen grip	-
	Finger guided	
	Sideways and rotate	
	Upside down and rotate	
	Laryngoscope/Bougie	
Additional maneuvers to position properly (over and above usual SAD insertion techniques)	Extra mouth opening	-
	Extra jaw thrust	
	Extra head extension	
Cuff seal with CuffPilot in green zone	Seals at >30 cmH2O	1
	Seals at >22.5 to 30 cmH2O	2
	Seals at 15 to 22.5 cmH2O	3
	Seals at <15 cmH2O, but with achievable ventilation	4
	Unable to ventilate despite good positioning	5
Need for SAD repositioning during case	Yes, and reason for repositioning	
	No	
SAD=Supraglottic Airway Device		

Table 1: Structure of Questionnaire.

Evaluation of predictors

For each case we recorded a number of other parameters defined as "predictors". These were categorized into patient, airway, operator, and technique-related predictors (Table 1). Patient-related predictors were patient sex and weight. Airway-related predictors were the Mallampati score (scored from one to four); thyromental distance (scored as an ordinal variable, with score of one meaning less than 6cm, score of two meaning 6 to 8 cm, and score of three meaning greater than 8 cm); dentition status (full set, partial set, or edentulous); and the size of the SAD used for the case (sizes 3, 4 and 5). Operator-related predictors were level of medical training (resident, registrar, or consultant) and prior experience with the Guardian (scored from one to three, with one meaning 0 to 4 times of prior Guardian use, two meaning 5 to 10 times, and three meaning greater than 10 times). Technique-related predictors were the level of cuff inflation (fully deflated, partially inflated, or fully inflated), insertion technique (sideways and rotate; pen-grip; upside-down and rotate; finger-guided; and multiple techniques), and extra airway maneuvers (jaw thrust; head extension; mouth opening; and multiple maneuvers).

Association between predictors and outcomes

We then assessed for any association between each predictor and success of insertion. We also looked at possible relationships between successful insertion and positive outcomes. These assessments were performed via Chi-square tests for categorical predictors, Kendall tau-c tests for ordinal predictors, and logistic regression for continuous predictors. Where appropriate, Spearman correlation was performed between predictors to look for confounding effects.

Statistical analysis

All statistical tests were performed using Predictive Analytics Software Statistics 22 (IBM Corporation, New York, 2013) and Microsoft Excel 2013 (Microsoft Corporation, Redmond, 2012). Graphs were plotted using GraphPad Prism 5 (GraphPad Software, La Jolla, 2007). In most cases, a result was considered significant if $p<0.05$ by two-tailed test. The exception was the use of a one-tailed test in comparing our observed success rate to an a priori success rate of 95%; we were only clinically interested if success rate was lower than this figure (see Sample collection).

Results

Outcomes

For this study we were able to collect a total of 67 cases. The general characteristics of this sample are described in Table 2, while the results for the outcomes of interest are described in Table 3. The overall success rate was 78%, which is significantly lower than an assumed a priori success rate of 95% ($p<0.0001$, one-tailed binomial test). The proportion of all cases where the number of insertion attempts was less than three was 89%. Also 66% of cases had an ease of insertion score less than three; 84% of cases had a CSP score of less than four (i.e. CSP greater than 15 cmH_2O); and 85% of cases did not require any SAD repositioning.

Property	Sample size	Value
Sex	67	34 female (51%)
Weight in kg; mean (SD)	61	81.1 (23.0)
Mallampati score[a]; median (IQR)	50	2 (1 to 2)
Thyromental score[a]; median (IQR)	51	2 (2 to 2)
SAD size; median (IQR)	66	4 (3 to 4)
Dentition status	51	39 full set (76%)
		8 partial set (16%)
		4 edentulous (8%)
Level of training of operator performing SAD insertion	65	8 by resident (12%)
		21 by junior registrar (32%)
		7 by senior registrar (11%)
		29 by consultant (45%)
Previous experience with GuardianCPV	67	13 with 0-4 trials (19%)
		14 with 5-10 trials (21%)
		39 with >10 trials (58%)

SD=Standard Deviation; SAD=Supraglottic Airway Device; [a]Mallampati score: 1=complete visibility of uvula; 2=incomplete visibility of the uvula; 3=visibility of soft and hard palate only; 4=visibility of hard palate only; Thyromental score: distance between thyroid notch and mentum (chin); 1=<6 cm; 2=6 to 8 cm; 3=>8 cm; Mallampati and thyromental scores are used by anaesthetists to judge airway dimensions and intubation difficulty.

Table 2: General characteristics of analyzed sample.

Outcome	Sample size	Value	Association with overall success
Overall success	67	52 (78%)	
Insertion attempts, median (IQR)	66	1 (1 to 2)	p=0.001
Insertion attempts <3	66	59 (89%)	p=0.032
Ease of insertion scorea, median (IQR)	67	2 (2 to 3)	p=0.01
Ease of insertion score <3	67	44 (66%)	p=0.003
CSPb score, median (IQR)	60	2 (1 to 3)	p<0.0001
CSP score <4	60	50 (83%)	p<0.0001
No SAD repositioning required	64	54 (84%)	p<0.0001

aEase of insertion score: 1=device slipping in without effort; 3=required additional assistance; 5=complete failure of insertion; bCSP=cuff seal pressure; CSP score: 1=>30 cmH_2O; 2=22.5 to 30 cmH_2O; 3=15 to 22.5 cmH_2O; 4=<15 cmH_2O but ventilation achievable; 5=no ventilation possible

Table 3: Outcomes of interest and relationship with success.

Successful insertion was significantly associated with fewer attempts at insertion, (p=0.001); easier insertion (p=0.012); higher CSPs ($p<0.0001$); and reduced need for SAD repositioning ($p<0.0001$).

Predictors of success

Statistical tests were performed to individually assess each predictor and its relationship with the success of each case; the results of these are summarized in Table 4.

Predictors	Association with overall success
Patient-related	
Patient sex	p=0.72
Patient weight	p=0.28
Airway-related	
Mallampati score	p=0.72
Thyromental distance score	p=0.38
Dentition status	p=0.06
SAD size	p=0.87
Operator-related	
Prior experience with the Guardian	p=0.049*
Training level of Guardian operator	p=0.18
Technique-related	
Degree of cuff inflation	p=0.18
Insertion technique	p=0.12
Type of extra airway maneuver used	p=0.11
SAD=Supraglottic Airway Device	

Table 4: Predictors of interest, and relationship with success.

Chi-square tests did not identify any significant relationship between success rate and patient sex (p=0.72) or weight (p=0.28). Neither was there any significant relationship between success rates and airway-related parameters, such as Mallampati score (p=0.72), thyromental distance (p=0.38) and SAD size (p=0.87). A mild trend was noted with dentition status (p=0.06): greater chances of success were observed with fewer teeth (100% for edentulous patients, *vs.* 71% for patients with full sets).

Previous operator experience with the Guardian was associated with greater chances of success (p=0.049). An 87% success rate was observed amongst those with an experience score of 3 (>10 times prior use of the Guardian), *vs.* 62% with experience score 1 (0-4 times prior experience). Also, Spearman correlation revealed a weak negative trend between experience with the Guardian and ease of insertion ($\rho(67)=-0.265$, p=0.030); those who had more experience appeared to give lower (i.e. better) scores for ease of insertion. There was no significant association between operator training level and success rate (p=0.18).

In terms of the level of cuff inflation (recorded n=63), 25 cases (40%) were fully deflated, 36 cases (57%) were partially inflated, and 2 cases (3%) were fully inflated. There was no significant relationship between degree of cuff inflation and success rate (p=0.18). Spearman correlation did not find any relationship between cuff seal pressure and degree of cuff inflation ($\rho(61)=-0.028$, p=0.832).

With regards to insertion technique (recorded n=67), the most popular techniques in descending order were sideways and rotate (52%); pen grip (25%); upside-down and rotate (10%); and finger-guided (6%); multiple techniques were used in the remaining 7% of cases. A Chi-square test did not identify any relationship between technique used and success rate (p=0.12). Overall, when used singularly, most of the techniques appeared to demonstrate a success rate of 75 to 88%; upside-down and rotate had a 100% success rate, but sample size was small (n=7).

In relation to extra airway maneuvers, 41% of cases did not require the use of any type of maneuver, while 59% required use of at least one maneuver (n=39). Of these 39 cases, the most popular maneuvers in descending order were jaw thrust (48%), head extension (13%), and mouth opening (10%); multiple maneuvers were used in the remaining 30% of cases. Chi-square testing did not identify any relationship between maneuver used and success rate (p=0.11).

Discussion

Context of this study

In general, the clinical evaluation of SADs is complicated by a number of practical limitations; the relative infrequency of difficult airways and airway complications often necessitates high-powered, multicentre studies [13], and the subsequent cost and difficulty renders such trials an unattractive option. Lately non-inferiority trials of airways devices have been employed [14]; these found that most popular second-generation SADs (i.e. LMA Supreme, i-gel, and Proseal LMA) yielded comparable or slightly superior results to the older SADs (i.e. LMA Classic) [15-19]. This may be due to features that distinguish second-generation SADs from first-generation, including improved pharyngeal and oesophageal sealing, and the presence of gastric drains and integral bite blocks. Second-generation SADs feature the separation of the gastrointestinal and respiratory tracts, which theoretically provides additional protection against aspiration [20]. Although the UK NAP4 Study currently recommends the use of second-generation SADs over older SADs [20], it is still not yet clear whether all second-generation SADs, particularly the Guardian, have the same performance overall. The ever-increasing market for airway devices poses the challenge of ensuring that each device is rigorously validated before widespread use.

At the time of conducting this study in 2013, there was only one previous study evaluating the efficacy of the Guardian, with a further study published after the completion of our study. Tiefenthaler et al. found that both Guardian and Supreme yielded 100% successful insertion rates (n=60 each) with trained anesthetists, and that the Guardian offered slightly superior OLP to the Supreme (31 *vs.* 27 cmH_2O, p<0.0001) [10]. Some limitations of this study include all patients being female and paralyzed, and all insertions having been performed by one of two consultant anesthetists experienced in the use of both models. The subsequent 2015 study by Pajiyar et al. showed 95% success rates of Guardian insertion with an insignificant difference to rates of Proseal insertion (n=40 each, p>0.05) with slightly superior OLP (32 *vs.* 29 cmH_2O, p<0.05) [11]. Limitations of this subsequent study were similar, with all patients being female and paralyzed. A number of other devices have been similarly trailed on patients undergoing surgery (Table 5). Our study contributes new data from a real-life application of this device in a tertiary teaching hospital.

	Compared Devices	First attempt success rate	P value	Oropharyngeal leak pressure (cmH_2O)	P value
Tiefenthaler et al.	Supreme	100%	N/A	27	p<0.0001
	Guardian	100%		31	
Pajiyar et al.	Proseal	97.50%	p>0.05	29	P<0.05
	Guardian	95%		32	
Belena et al.	Supreme	96.70%	p<0.01	26.8	p<0.01
	Proseal	71.20%		30.7	
Lee et al.	Supreme	94%	p>0.05	27.9	p<0.01
	Proseal	91%		31.7	
Eschertzhuber et al.	Supreme	95%	p>0.05	21-28	p<0.0001
	Proseal	92%		29-34	
Ragazzi et al.	Supreme	77%	p<0.05	29	p<0.01
	i-gel	54%		23	
Chew et al.	Supreme	97.80%	p>0.05	25.6	p<0.001
	i-gel	93%		20.7	
Teoh et al.	Supreme	94%	p>0.05	26.4	p>0.05
	i-gel	96%		25	

Table 5: Comparison with other supraglottic airway devices.

Outcomes with the guardian

Our study found that the success rate achieved at TNH with the Guardian (78%) was lower than that documented in Tiefenthaler et al. (100%) [10] and significantly lower than a reasonable rate of 95%; it was otherwise more comparable with other success rates observed for other second-generation SADs, such as the Supreme [1-3,5,6,9], the previous SAD model employed at TNH. Success with the Guardian was associated with perceived ease of insertion, higher seal pressures, and reduced need for SAD repositioning. Greater than 80% of all cases had positive outcomes with insertion attempts, CSPs, and repositioning requirements. However, ease of insertion remained a problem (66% positive outcome). Our operators subjectively described difficulty passing the tip through the oropharynx, due to the extra length and rigidity of the cuff. All this suggests difficulty with Guardian insertion as a key problem for the staff at TNH.

Experience was a key predictor for success with the guardian

Analysis identified a significant relationship between prior experience with the Guardian and subsequent successful insertion (p=0.049). Those with more experience with Guardian (experience score 3, i.e. greater than 10 times prior use of the Guardian) appeared to achieve higher success rates (87%). This appears to suggest a "learning effect", and that further training and familiarization with the Guardian may ameliorate some of the difficulties experienced by the staff. This is somewhat supported by the statistically-significant correlation between experience and perceived ease of insertion-those who had more experience appeared to find the Guardian easier to insert. It is likely that the differences in outcome between this study and Tiefenthaler et al. differ due to the increased heterogeneity in population and operator experience in our study.

Trends in insertion techniques with the guardian

Our study identified that the most popular insertion technique for TNH staff was sideways-and-rotate. This was in contrast to the technique reported in Tiefenthaler et al. where both operators in the paper exclusively used a finger-guided technique [10]. The original manufacturer, Ultimate Medical, also recommended using the finger-guided technique for their product (AM Keogh, personal communication). This difference in technique may have had some bearing on overall success rates, although our analysis did not show any significant association between insertion technique and success rates.

Other examined factors did not factor significantly into success with the guardian

Other patient, airway, and technique-related factors did not appear to have any significant impact on success with the Guardian. We did note that edentulous cases tended to have somewhat higher success rates compared to cases with full teeth sets.

Context of questionnaire

The impracticalities of fully studying, in a well-controlled randomized manner, the safety and efficacy of a new device recently

introduced in the hospital setting makes it challenging to be done [21], especially routinely. Limited published literature or ones that have potential conflicts of interests, in the form of device manufacturer funding etc., make it difficult for both the hospital and clinicians to determine the suitability of the device for their setting [21,22]. Our study takes into account the heterogeneity of patient population in a tertiary hospital setting with various levels of experiences of the operators, compared to the existing papers. The questionnaire was designed to be broad in order to suitably address these issues, as well as to be able to identify as many factors that may prove of significance for further follow-up or future studies. Key findings from this study can serve as a launching pad or be a study pilot that can assist in more exhaustively investigating factors of interest or significance.

Limitations

This pilot study has successfully identified several limitations, which will contribute to constructing an improved framework for the follow-up study. The non-compulsory nature of case recruitment introduced an element of volunteer bias. Case reporting in the questionnaires, though performed soon after recruitment, was still retroactive and therefore subject to recall bias. The small sample size (n=67), sufficient in identifying significant differences in overall success rates, may have been underpowered to identify subtle relationships between predictors and outcomes. For this particular pilot study, cases with multiple insertion attempts featured the same operator, with the experience level as reported; however, in realistic clinical situations, this is unlikely to be always the case, as an operator who encounters difficulty will likely seek assistance from other more experienced staff. It would be of particular interest to document help-seeking for future studies, as this will reduce selection bias associated with non-reporting of failure amongst junior and less-experienced operators. Finally, it may be useful to seek information on anesthetic procedure in future studies, given that this may also affect ease of insertion of SADs.

Due to practical limitations within this study, much of the data collected had to be re-organized as categorical or ordinal variables, rather than continuous variables. For instance, thyromental distance and CSP had to be converted to ordinal data due to the limited accuracy of measuring implements in theatre. With these limitations in mind, a follow-up study would benefit from the inclusion of a comparison device with an adequately powered sample size and revised questionnaire.

Conclusions

In conclusion, our pilot study demonstrated that the Guardian SAD was comparable in efficacy to other SADs, although not as effective as previously reported by Tiefenthaler. There were perceived difficulties in inserting the Guardian, but there was some evidence that further training and acclimatization to the device could reduce difficulty and increase success rates. Our study paves the way for a follow-up study of this SAD model. The questionnaire had been designed to be suitably broad which had successfully identified key factors of both interest and significance that should aid in streamlining further follow-up studies regarding the Guardian SAD. Ideally, proper auditing and familiarization with new airway devices should take place prior to mass uptake in the clinical setting. However, given that this may prove impractical in the hospital setting, a questionnaire designed similar to ours may assist in identifying safety and efficacy rates of new devices. We should note this study has influenced, in part, to the clinical decision to replace the Guardian SAD with another that had been proven more successful.

Declarations

Ethics approval

Ethics approval was obtained from the Northern Health Human Research Ethics Committee (LR 09.2014) via the low-risk pathway.

Availability of data and materials

Our collected paper data is kept in locked research filing cabinets and will be stored as per ethics requirements. Our electronic data is stored on a secured electronic server.

Competing interests

All authors have no conflicts of interest to disclose.

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Authors' contributions

MHL performed data collection and was involved in drafting of the paper. HFT performed statistical analyses and was involved in drafting of the paper. CJB was involved drafting of the paper. JKC was involved in conceptual design and supervision of the project. All authors read and approved the manuscript.

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