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## Using the literature to quantify the learning curve: A case study

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Short title: Quantifying the learning curve

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## **ABSTRACT**

**Objective:** To assess whether a literature review of a technology can allow a learning curve to be quantified.

**Methods:** The literature for fiberoptic intubation was searched for studies reporting information relevant to the learning curve. The Cochrane Library, Medline, Embase and Science Citation index were searched. Studies that reported a procedure time were included. Data were abstracted on the three features of learning: initial level, rate of learning and asymptote level. Random effect meta-analysis was performed.

**Results:** Only 21 studies gave explicit information concerning the previous experience of the operator(s). There were 32 different definitions of procedure time. From 4 studies of fiberoptic nasotracheal intubation, the mean starting level and time for the 10<sup>th</sup> procedure (95% confidence interval) was estimated to be 133s (113, 153) and 71s (62, 79) respectively.

**Conclusions:** The review approach allowed learning to be quantified for our example technology. Poor and insufficient reporting constrained formal statistical estimation. Standardised reporting of non-drug techniques with adequate learning curve details is needed to inform trial design and cost-effectiveness analysis.

**Keywords:** Randomized controlled trials, learning, clinical competence, literature review

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## INTRODUCTION

A learning curve can be defined as an improvement in performance over time. This improvement tends to be most rapid at first and then tails off over time. Three main features of a learning curve can be recognised. An *initial or starting level* defines where the performance level begins. The *rate of learning* measures how quickly a particular level of performance is reached. Lastly, the *asymptote or expert level* is the level at which performance stabilises (see Fig 1). Learning curves have been observed for many health technologies (such as minimal access technologies), but rarely quantified.(15)

Poor quantification of learning curves can complicate the design of randomised trials of non-drug technologies. Trials are often designed with limited evidence of learning curve features available, which leaves the trial open to criticism that insufficient account of learning had been taken. Concerns over the presence of a learning curve have particularly hindered surgical trials.(11) Current design approaches to overcome learning curves, such as operators performing a fixed number of procedures before being eligible to participate or 'expertise' trials(4), are often based upon poor evidence and do not necessarily protect studies from criticism(1;5). One possible approach to increase understanding of the learning curve for a specific technology is to review the technology's literature, abstracting details of the features of the learning curve. In this paper, we illustrate how a literature review of the learning curve can yield information about the nature of learning of a specific technology. Limitations in reporting which hamper

this approach are highlighted and guidance for future research in this area is given.

### **Example technology - Fiberoptic (tracheal) Intubation**

Fiberoptic tracheal intubation is a technique for the management of the airway and is used for many patients who present difficulties with conventional intubation. Fiberoptic intubation is substantially different from the conventional technique, requiring new practical skills to be learned.(2) A number of studies have shown that fiberoptic intubation takes longer than conventional intubation(19) and the most common cause for a failed fiberoptic intubation has been identified as a lack of training or experience.(13) Lack of expertise has been suggest as the main reason for the current underutilisation of the technology in 1<sup>st</sup> world countries.(10) Despite improved training programs, there is evidence that operators are still increasing their proficiency after initial training.(2;14;17;18) The time taken to perform intubation, the procedure time, is an important outcome measure since long procedure times are acknowledged to be associated with increased risk of morbidity.(20)

## **METHODS**

### **Search strategy**

A search strategy was developed in Medline (up to December week 4 2000) and adapted for use in Embase and Science Citation index. The Cochrane

Library (2001 issue 1) was checked for relevant reviews. A number of terms were identified for selecting papers which had reported procedure times, especially those that had evaluated operator experience. Differences between British and American spellings were taken into account. Language restrictions were not made. The abstracts of potential papers generated by the search were assessed to identify suitable studies. If the abstract established the relevance of the paper or there was a high likelihood of this, the full paper was acquired. The full papers were checked and approximately 5% were assessed by a second reviewer. The bibliographies of included papers were scanned for additional papers for inclusion.

### **Inclusion criteria**

Randomised controlled trials (RCTs), crossover trials, controlled clinical trials, cohort studies and case-series studies were included. All studies that used fiberoptic (nasal or oral) tracheal intubation on adult patients (aged 16+) and reported a procedure time were included. Studies were not excluded for use of unorthodox equipment as long as this was not deemed to alter the technique substantially.

### **Assessing learning**

The primary outcome was the procedure time in seconds. Data were abstracted on the equipment used, timing definition, the experience of the operators and any information relating to the starting level, rate of learning and asymptotic (expert) level. A consultant anaesthetist identified groups of

studies that used similar equipment and timing definitions. Abstracted data were recorded on a specially developed form. Where possible, starting level, rate of learning and expert level were combined across studies. As some heterogeneity between study estimates was expected DerSimonian and Laird random effects method was used.(3) Pooled estimates along with 95% confidence intervals (CIs) were calculated using STATA software release 9.2.

## **RESULTS**

### **Description of studies**

The database searches produced 499 references: 338 from Medline, a further from 134 Embase and 27 from Science Citation. No relevant reviews were found in the Cochrane Library. The number of references from each database reflected the order in which they were searched. Of the 499 references, 89 were identified for further investigation and full papers were retrieved. After assessment, 39 studies were included in the review. An additional 7 papers were identified from references as possibly being relevant, and of these four were included giving a total of 43 included studies.

The majority of the included studies (58%) were European, with eleven from North America, five in Asia and one from Australia. Of the included studies, there were twenty-two RCTs, eleven case-series/cohort studies, nine

controlled trials and one crossover trial. Fiberoptic intubation was compared with at least one type of conventional intubation in 16 studies. A single fiberoptic intervention group was investigated in 29 studies, two or more fiberoptic intervention groups were compared in 14 studies.

### **Procedure time**

All 43 papers reported the time taken to perform fiberoptic intubation. A definition of how the time was recorded was given in 41 papers with 32 different definitions stated. A variety of different equipment was used between studies. The studies were grouped according to whether they had performed nasotracheal or orotracheal fiberoptic intubation.

### **Operator experience**

Of the 43 studies, 21 gave explicit information concerning the previous fiberoptic experience of the operator(s). Nine reported no prior experience, seven commented on experience (for example “skilled” or “relative novice”), four gave the number of procedure previously performed, and one reported the experience in terms of the number of years undertaking procedures.

Three studies commented on experience of non-fiberoptic intubation techniques but did not explicitly state no prior experience of fiberoptic intubation. In nine studies, only the professional status of the operator was given. The use of the term ‘anaesthetist’ was assumed to imply that the person was experienced with conventional intubation. Ten studies did not



give any explicit information about the operator(s) experience level or professional status. It was likely that the respective authors, who were anaesthetists, performed the intubations and were therefore experienced in conventional intubation.

### **Combining features of the learning curve**

Given the differences between equipment used and the variation in definitions of timing, only two subsets of the studies were considered sufficiently homogeneous by a consultant anaesthetist for grouping together.

#### *Nasotracheal fiberoptic intubation*

The times of four studies (all case series) were considered suitable for combining.(2;14;17;18) These studies, all with the same principal author, used the same equipment to perform nasal fiberoptic intubations in at least one intervention group. All operators had a similar level of prior experience and had not performed a 'real' fiberoptic intubation before. The definition of procedure time was also consistent between studies. The four series of intubations are shown in Figure 2. All four series suggested that there was a reduction in the procedure time as the experience of the operator increased.

There was variation in the initial time point between studies (ranging from 112 to 178). Pooled mean procedure times for the initial level was 133s 95% CI (113, 153). The number of intubations performed in each study was low and variable making it unlikely that the expert level was attained. Pooled mean

procedure times for the 10<sup>th</sup> intubation was 71s 95% CI (62, 79), though the final data point in Smith et al.(17) suggests that a lower level was achievable. This paper gave an estimate of 35s for the asymptote in one paper. Three studies stated a value of 45, for the number of intubations required to reach the asymptote level(2;17;18), two referencing the third.(17) Two papers gave a half life of 9 intubations.(2;17)

### *Orotracheal fiberoptic intubation*

The times of three case series studies were considered suitable for combining.(9;16;18) A further study, compared experienced (consultant) versus inexperienced operators (trainee).(8) Though standardised within study, the level of training varied substantially across studies. None of the operators in the case series studies had previously performed fiberoptic intubation. The procedure time was recorded in a standardised way. The three case series of intubations are shown in Figure 3 and suggested that there was a reduction in the procedure time as the experience of the operator increased.

There was large variation in the initial level between studies (ranging from 88 to 240). Pooled mean procedure times from the three case series studies for the initial level was 81s 95% CI (49, 112). A measure of the rate of decrease was given as a straight line with a slope of -6.0s per intubation (intercept of 106 seconds) over the first 10 procedures.(16) One study quoted 45 as the approximate number of intubations required to reach the asymptote level;

however that estimate was quoted from a nasotracheal intubation study.(7)  
The number of intubations performed in each case series study was again low making it unlikely that the expert level was attained. Pooled mean procedure times for the 10<sup>th</sup> intubation was 51s 95% CI (37, 66). The data from the comparative study demonstrated a mean expert level of 33s and the final datapoints from the case series suggest a level around 40s was achievable.

## DISCUSSION

We have demonstrated that it is possible to quantify a learning curve for a health technology using a systematic literature review approach. This approach could inform the design of randomised trials where an operator's 'prior expertise' is a necessary design feature.<sup>(4)</sup> Substantial learning was observed for fiberoptic intubation which has implications for the design and analysis of clinical trials in this area. Similar magnitude effects may well occur in other technologies. For some techniques, such as novel surgical procedures, learning curves may be particularly important. Clinical trials that fail to quantify and report the learning curves expose themselves to criticism and their results will as a consequence be less convincing. This criticism also applies to cost-effectiveness analysis where learning could impact upon estimates of cost as well as effectiveness. The net effect of learning on cost is uncertain as although we may, a priori, expect more experienced operators to have higher effectiveness (for example, shorter procedure times and length of hospitalisation), more experienced operators will be more costly.

Expertise trials<sup>(4)</sup> can be criticised because 'expertise' is often poorly defined. The use of a fixed number of procedures prior to operator participation can be similarly criticised. The approach outlined here provides an alternative evidence based method to incorporate learning curve features in trial design. The estimates produced by this approach provide an average measure of learning which can be used to define the required level of expertise.

Individual operator differences will persist in the trial which should be accounted for by an appropriate statistical method.(1)

The existence of operator learning has been widely reported for fiberoptic intubation, but few papers gave any details on the prior experience of the operators. Even when some information was given it was often unclear exactly what the level of experience actually was. Only one study which reported an operator as 'experienced' quantified the statement by stating that the number of intubations previously performed (30 intubations).(6) One study recommended just 10 intubations for a operator to achieve 'an acceptable level of technical expertise'.(9) We recommend that the level of experience should be reported as fully as possible, in lieu of a better measure, the number of procedures previously performed by each operator should be stated along with details of any prior training received.

The procedure time is an important measures of the value of an intubation technique, not only in terms of the use of medical staff time but also in respect to the potential harm to the patient. Prolonged times have increased risk of morbidity and in rare cases even death can result. The lack of consistency in the procedure time is a barrier to adopting the review approach to assessment of learning. The number of different approaches to fiberoptic intubation and the variety of equipment available exacerbated this problem. Ideally, the process and timing of fiberoptic intubation should to be standardised using a definition that is suitable for different approaches to fiberoptic intubation.

### **Learning curve for fiberoptic intubation**

The pooled estimates from the review suggested that performing 10 intubations (oral or nasal) probably accounted for a large part of the learning curve, but little information was given in the literature concerning the asymptotic level of performance or the rate of progression. The handful of case-series which were reported were too short to be conclusive, but were suggestive that times could be improved by a further 20 seconds.

### **CONCLUSIONS**

Learning curves can have a major impact on trial design and on the subsequent reporting and interpretation of the results. The review approach allowed learning to be quantified for our example technology, which in turn informs trial design and cost effectiveness analysis. However, poor and insufficient reporting constrained formal statistical estimation. Standardised reporting of nondrug technologies (such as an extension of CONSORT statement(12)) should be developed to improve the overall reporting and level of consistency. This could incorporate aspects relevant to the ascertainment of a learning curve such as procedure methodology, inconsistency in timing and the reporting of operator experience.

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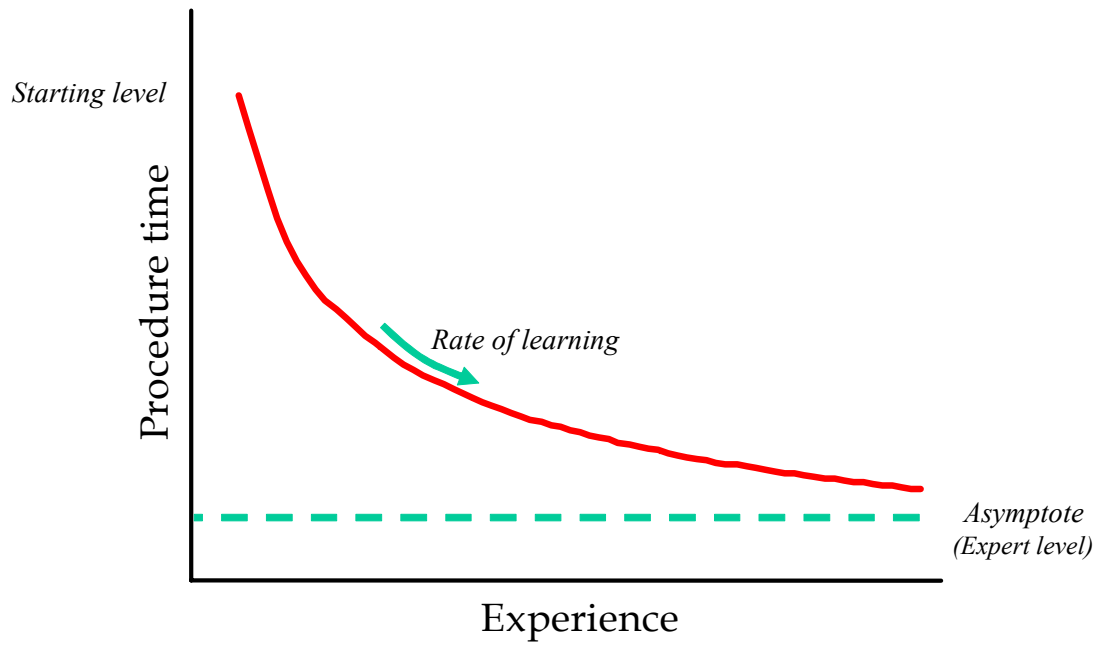
## **Legends to Figures**

Figure 1. Features of a learning curve

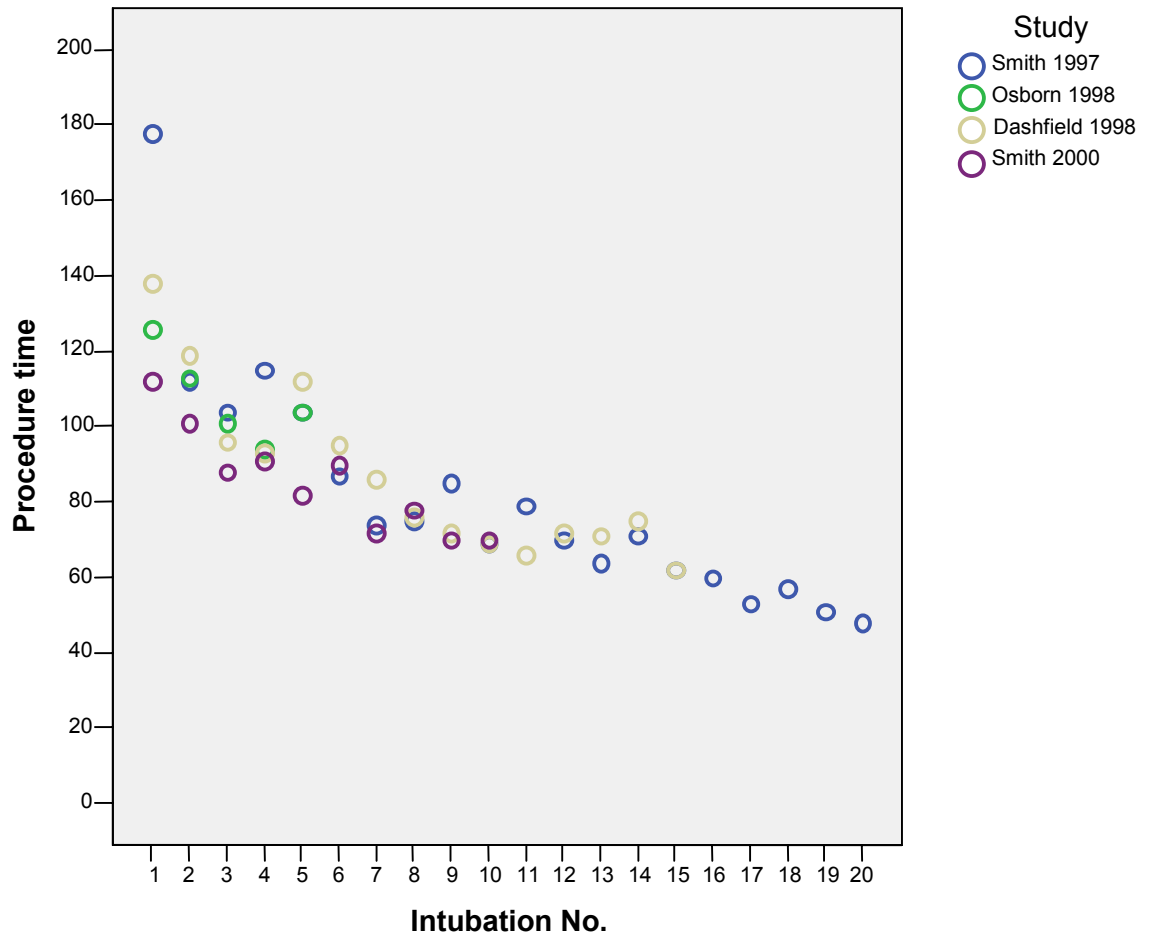
Figure 2. Four nasotracheal fibreoptic tracheal intubation case series

Figure 3. Three orotracheal fibreoptic tracheal intubation case series

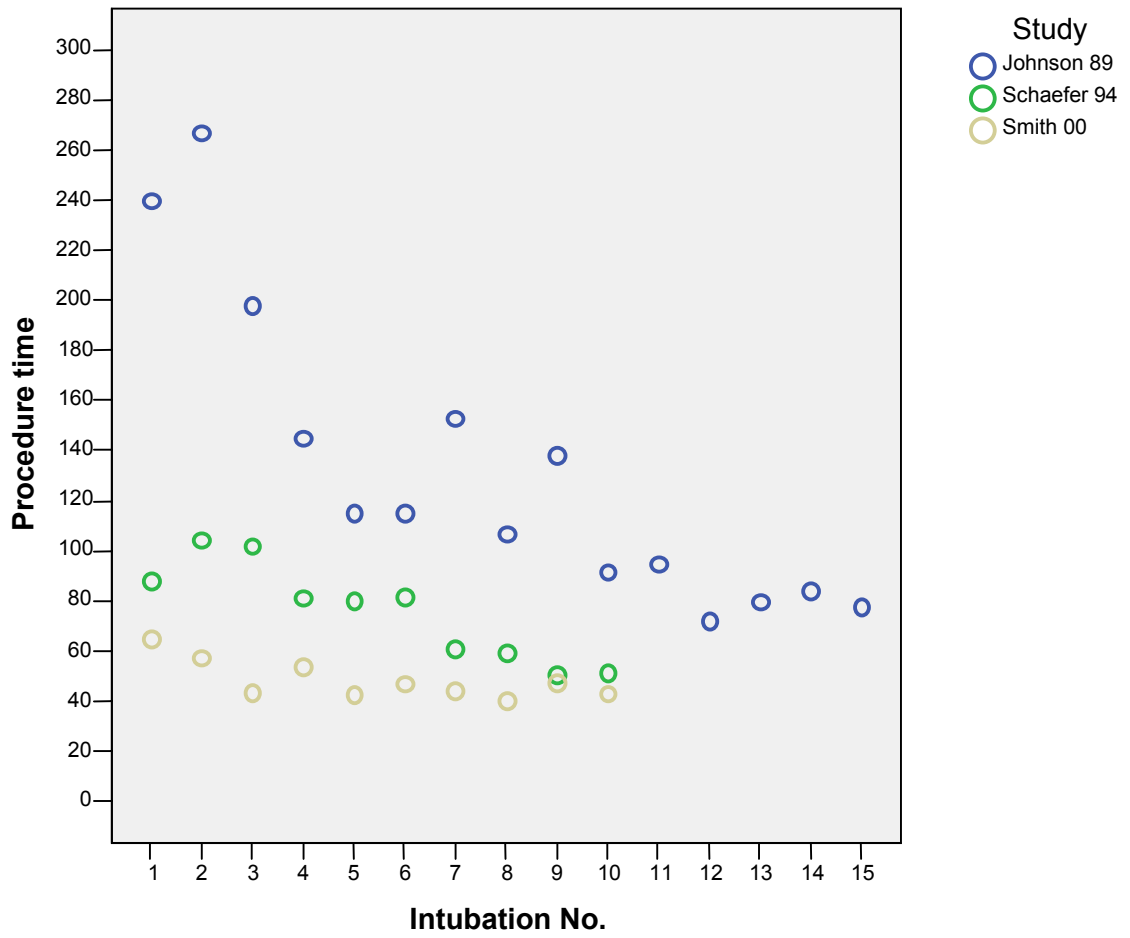
**Figure 1.** Features of a learning curve



**Figure 2.** Four nasotracheal fiberoptic tracheal intubation case series



**Figure 3.** Three orotracheal fiberoptic tracheal intubation case series



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## DEFINITIONS OF TIME TO PERFORM PROCEDURE

### Orotacheal Intubation

#### *Definition of procedure time*

Procedure time reported but no time definition given

Time between removal of facemask to connection of the breathing system after intubation

Time between removal of facemask to reappearance of a normal expired CO<sub>2</sub> trace on the capnograph after reventilation after intubation

Time between removal of facemask and when the endotracheal tube was placed in the trachea with the cuff inflated

Time from insertion of the intubating instrument into mouth to connection of the tracheal tube to the breathing circuit

Tracheal tube's tip level with teeth to successful placement

Insertion of scope into mouth until fibreoptic stylet scope was removed from endotracheal tube

Placement of scope and tracheal tube in intubating laryngeal mask tube and success intubation

Laryngeal mask in place until the endotracheal tube is in place

Airway device introduced into the mouth to confirmation of successful intubation

Start of fibrescopy to first evidence of CO<sub>2</sub> in breathing system on the inserted tracheal tube

Loss of CO<sub>2</sub> (disconnected circuit) to reappear CO<sub>2</sub> from tracheal tube

Fibrescope from the lips to the carina (details given of anatomical features to be visualised)

Scope introduced to confirmation of the correct position of the tracheal tube by capnography

Device inserted into the oropharynx and the detection of end-tidal CO<sub>2</sub>

Device inserted into the oropharynx and air was inflated into the cuff

Initial introduction of the device to the removal of scope from the airway

Time for laryngoscopy and intubation

Time to correct placement of tracheal tube

Time from introduction of instrument until the end-tidal CO<sub>2</sub> was recorded

Starting to advance the tracheal tube to withdrawing the scope from the mouth

Just about to insert the scope into the mouth to breathing system connected and the presence of CO<sub>2</sub> indicated by capnography

Removal of the facemask to the insertion of the fibrescope into the trachea

Initial insertion into orophaynx to direct observation of endotracheal tube is advancement through the vocal cords

Last breath by mask to first breath via the endotracheal tube minus the time during which repeat mask ventilation was performed

Time separating the withdrawal of the mask allowing initial ventilation and the moment when the intubation tube is correctly placed in trachea with balloon inflated

### **Nasotracheal Intubation**

#### *Definition of procedure time*

Procedure time reported but no time definition given

Time between removal of facemask to connection of the breathing system after intubation

Time between removal of facemask to reappearance of a normal expired CO<sub>2</sub> trace on the capnograph after reventilation after intubation

Fibrescope from the first nostril examined to the carina (details given of anatomical features to be visualised)

Scope enters the tracheal tube until correct placement confirmed by end-tidal CO<sub>2</sub> pressure greater than 3.3kPa

Time taken for tracheoscopy

Time taken for endoscopy

Time from loss of eyelash response to tracheal intubation

Time from insertion into the nose to visualisation of the larynx

Time from insertion of the fibrescope to completion of intubation