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A Delphi Consensus report from the "Prolonged Air Leak: A Survey" study group on prevention and management of postoperative air leaks after minimally invasive anatomical resections

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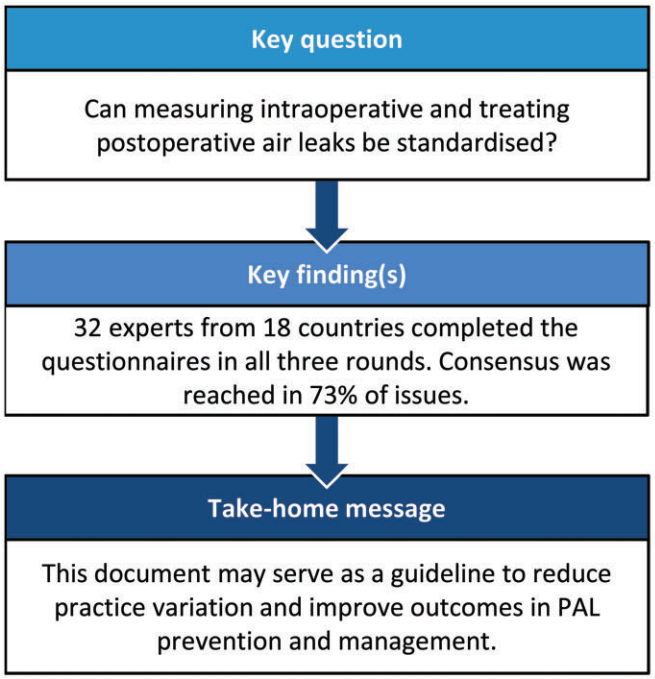

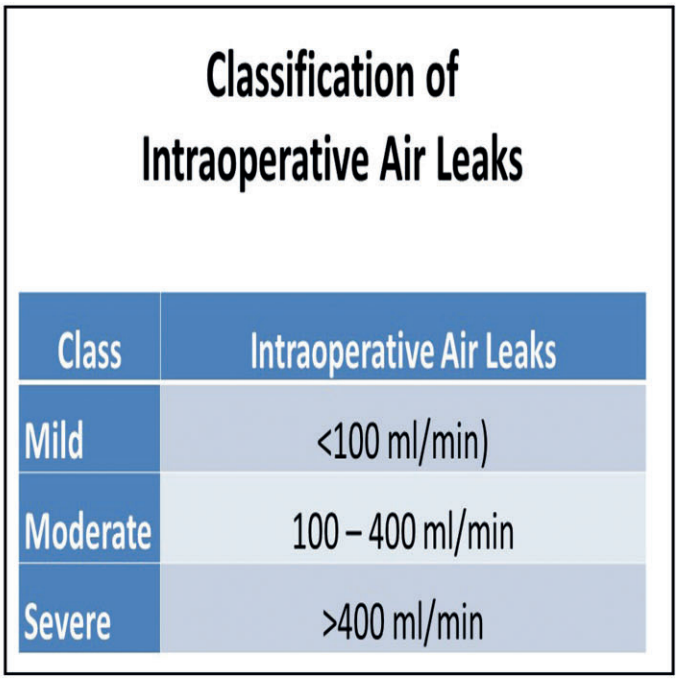

Abstract

OBJECTIVES: This study reports the results of an international expert consensus process evaluating the assessment of intraoperative air leaks (IAL) and treatment of postoperative prolonged air leaks (PAL) utilizing a Delphi process, with the aim of helping standardization and improving practice.

METHODS: A panel of 45 questions was developed and submitted to an international working group of experts in minimally invasive lung cancer surgery. Modified Delphi methodology was used to review responses, including 3 rounds of voting. The consensus was defined *a priori* as >50% agreement among the experts. Clinical practice standards were graded as *recommended* or *highly recommended* if 50–74% or >75% of the experts reached an agreement, respectively.

RESULTS: A total of 32 experts from 18 countries completed the questionnaires in all 3 rounds. Respondents agreed that PAL are defined as >5 days and that current risk models are rarely used. The consensus was reached in 33/45 issues (73.3%). IAL were classified as mild (<100 ml/min; 81%), moderate (100–400 ml/min; 71%) and severe (>400 ml/min; 74%). If mild IAL are detected, 68% do not treat; if moderate, consensus was not; if severe, 90% favoured treatment.

CONCLUSIONS: This expert consensus working group reached an agreement on the majority of issues regarding the detection and management of IAL and PAL. In the absence of prospective, randomized evidence supporting most of these clinical decisions, this document may serve as a guideline to reduce practice variation.

Keywords: Postoperative air leaks • Lobectomy • Segmentectomy • Lung cancer • Consensus • Delphi methodology

ABBREVIATIONS

AL	Air leaks
IAL	Intraoperative air leaks
MVT	Mechanical ventilation test
PAL	Prolonged air Leaks

INTRODUCTION

Prolonged air leak (PAL) after pulmonary resection is a common complication, with a significant impact on the duration of the hospital stay after surgery. The first attempts to classify PAL were published 20 years ago [1–3]. Recently, many authors have proposed a risk score to assess the probability of PAL [4–7]; however, a consensus has not been reached [8].

To improve the practice standardization in PAL cases, an international Delphi Consensus Study was designed to answer the following questions:

1. What is the definition of PAL?
2. Which tool is recommended to identify and quantify intraoperative air leaks (IAL)?
3. Which IAL do we need to treat?

4. What is the best treatment for IAL?
5. What is optimal chest tube management in PAL cases?
6. What is the best postoperative management in PAL cases?

This study reports the results of this process.

MATERIALS AND METHODS

Ethics statement

The IEO Ethical Committee waived the necessity of specific consent, considering that the activities carried out are part of the normal care activity and the patient is sufficiently informed through the institutional information and consent forms.

Methods

The working group was convened and organized by the Prolonged Air Leak: A Survey (PALAS) research team. The 32 working group members consisted of thoracic surgeons invited to participate voluntarily by the project team, which coordinated the process. The working group members represented academic centres, large teaching hospitals and community hospitals from Europe, North America, Brazil, Asia and Africa. The working group was designed to reduce the gender bias balance, and the seniority (years for the end of the residency) was balanced. Only 1 subject (in 33 contacted) disagreed with the participation in the working group. The Delphi methodology enables the development of consensus among experts, utilizing anonymity to avoid 1 expert's dominance, an iterative procedure to accommodate changes of opinion in different rounds, and precise feedback for the expert by revealing responses of the previous round. Several studies have demonstrated the value of the Delphi method, mainly when high-level evidence such as randomized controlled trials is unavailable [9]. The ideal number of participants required to obtain consensus using the Delphi methodology is unknown [10]. Therefore, the number of experts selected was based on the Delphi methodology's prior experiences and the expected response rate [9].

The questions were developed by Luca Bertolaccini and Francesco Zaraca and were not set to the expert beforehand. An individualized email invitation with 45 questions was sent to each expert linked to a secure website (Welphi Platform; https://www.welphi.com). Luca Bertolaccini coordinates the questionnaires rounds since the panellist were not aware of each other reasons. To strengthen the validity of the process, 3 rounds of voting were used. The invitation for the first round of voting was sent in June 2021 with 2 reminder emails before the closure of the first round of voting. An email invitation to view the first-round results and concomitantly participate in the second Delphi round was sent in July 2021, followed by 2 reminder emails. An email invitation to view the results of the second round of voting and concurrently participate in the third round of voting was distributed in September 2021, and 2 reminder emails were subsequently sent. Anonymous responses to the questions in the 3 rounds were tabulated into a centralized database. The experts did not have access to the opinions of the other experts. The results from the third round of voting formed the basis for the current consensus.

Statistical analysis

Descriptive statistics were used to summarize the results, and a de-identified summary was circulated to participants along with the following survey round. Respondents were encouraged to consider the results of their colleagues in each iterative round when answering. Distributions of the score for all parameters were measured along with calculated means. The consensus was defined *a priori* as >50% agreement among the panel of experts. The clinical practice was *recommended* if 50–74% of the experts reached an agreement and *highly recommended* if 75% or more of the experts reached an agreement [9]. Given the small sample size of respondents, subgroup analysis was not possible. There were no missing answers since all the answers were mandatory. There was no confidential information required for this study. Ethics committee approval was not required due to the nature of the study. Categorical data were reported as frequency, number and percentage. Ceiling effects could not be assessed given the small numbers of expert participants [11]. Data were collected prospectively. The standard, *EZR, irr, rcmdr* and *ROC* packages were used in RStudio (R Version 4.1.2, *Bird Hippie*) for statistical analysis [12, 13].

RESULTS

Overall, 32 experts from 18 countries completed all 3 rounds' questionnaires. PAL was defined as lasting longer than 5 days (87%) (Supplementary Material, Table S1). Regarding preoperative assessment, most of the participants (87%) do not preoperatively use any predictive PAL risk scores and 68% define PAL risk scores as only sometimes dependable and valuable.

Regarding IAL after VATS anatomical resection, 65% of experts perform a visual submersion test (Supplementary Material, Table S2); 32% routinely and 51% selectively perform a mechanical ventilation test (MVT = the difference between inspired and expired tidal volume) [14]. IAL was classified as mild (<100 ml/min; 81%), moderate (100–400 ml/min; 71%) and severe (>400 ml/min; 74%).

Regarding intraoperative treatment (Supplementary Material, Table S3), 68% of the respondents treated the IAL (particularly in high risk for cardiopulmonary complications patients) if detected with a submersion test. If mild IAL are detected with MVT, 68% do not treat; if moderate, consensus was not reached among participants; if severe, 90% of the respondents favoured treatment.

Technically, 81% usually prefer parenchymal suturing, and 55% usually prefer sealants. When performing anatomical resections in high-risk patients, 74% of respondents use sealants. Nevertheless, there was no consensus to support the use of sealants routinely after completing an anatomical resection.

Regarding chest tube management, 87% use a single tube and 58% prefer 24 Fr (Supplementary Material, Table S4). Digital drainage systems were preferred in 61%; however, there was no consensus on the evidence in the literature to support its use. On the other hand, 77% recommend the digital drainages to reduce the inter-operator differences in evaluating air leaks (AL) and the overall drainage duration.

There was no consensus regarding the threshold of serous drainage for removal; 68% of respondents do not discharge patients with chest tubes if the liquid output is too high to remove. There was no consensus about the minimum number of hours needed to wait before chest drain removal without AL. The

Table 1: Stratification of unselected patients into 3 classes based on the type of intraoperative alveolar air leak at the mechanical ventilation test and management recommendation

Class	Intraoperative alveolar air leak	Expected PAL without treatment	Recommendation
I	Mild (<100 ml/min)	Few hours	No treatment *Recommended*
II	Moderate (100–400 ml/min)	5.04 (SD = 3.63) days	Treatment in high-risk patients for cardiopulmonary complications *Highly recommended*
III	Severe (>400 ml/min)	≥15 days	Treatment *Highly recommended*

PAL: postoperative air leak; SD: standard deviation.

absence of AL was mandatory for chest tube removal in 65% of respondents; 52% discharge patients with chest tubes if the AL is too high to remove. Nevertheless, this decision is based more on the social/demographic/geographic issues than on the perceived reliability of valves' functionality.

Regarding the postoperative management of PAL (Supplementary Material, Table S5), there was no consensus on the technique to be used in the case of PAL that cannot be managed by water seal alone. The waiting time prior to treatments of prolonged PAL is reported in Table 1. Sudden start or increase of a large AL in a patient with previously absent or minimal AL was considered an indication for reoperation by 65% of the respondents. Table 2 reports the summary table of recommendations. The clinical practice is recommended if >75% of the experts reach an agreement.

DISCUSSION

After the results of a randomized controlled trial [15], the authors and the international faculty of an international meeting feel the need to create a study group. The PALAS group arose from the lack of consensus and evidence on many aspects of PAL after anatomic lung resection. Every participating expert from 18 countries completed all 3 rounds' questionnaires. The objective of this modified Delphi process was to reach a consensus on the definition of PAL; the usefulness of preoperative risk predictor models; the identification, quantification, and classification of IAL; intraoperative treatment of AL; chest tube management; and postoperative management of PAL.

It is *highly recommended* to define PAL as longer than 5 days. Due to the low clinical relevance of this definition, it might be debated whether other definitions like home discharge with chest tube/Heimlich valve would be more appropriate. We have recently demonstrated that current risk models do not have sufficient discriminatory capacity to be used in standard clinical practice due to the high rate of false positives [8]. Our current survey results confirm our study because 87% of participants do not use them, and 68% define them as only sometimes reliable and valuable. According to our results, it is *recommended* to detect IAL through a visual submersion test after minimally invasive anatomical resection. In addition, 83% of participants perform an objective measurement of intraoperative air leakage using MVT: 32% routinely and 51% selectively, if the surgeon deems it necessary. The MVT is *highly recommended* in selected cases.

We proposed to confirm a novel IAL classification [14–16]. The consensus was reached that an IAL at MVT should be classified as mild (<100 ml/min; 81% agreement), moderate (100–400 ml/min; 71%) and severe (>400 ml/min; 74%). Takamochi *et al.* [17], in support of our classification, demonstrated that only peak air loss >100 ml/min during the first 24 h after surgery was significantly helpful in predicting PAL after lung resection, and postoperative loss <100 ml/min was usually self-limiting. The MVT, in conjunction with other significant pre- and intraoperative risk factors, may improve the discriminatory capacity of current risk models for PAL [14, 18]. In the presence of IAL at submersion test, 68% of respondents decided to treat only in high-risk patients, whereas 13% would treat them in any patient. In the presence of mild IAL at the MVT, 68% feel confident that they are self-limiting and do not treat them; 19% would only treat high-risk patients; and 10% would treat all. In the case of moderate IAL, 48% would treat all and 39% would treat only high-risk patients. Takamochi has shown [17] that in patients with PAL >100 ml/min and an FEV1 <70%, PAL can be predicted. In our survey, if we add up answers B and C, we can state that in the case of moderate IAL in high-risk patients for cardiopulmonary complications, 89% of the participants would treat them if PAL is expected according to the local standard. It was underlined that the occurrence of PAL is linked to other postoperative adverse events [19, 20]. Brunelli *et al.* [18] demonstrated that unselected patients submitted to lobectomy with an IAL >500 ml/min measured after resection would have an expected AL duration of 15 days. With a consensus of 90% agreement, the survey confirms that intraoperative treatment in these cases is highly recommended.

Experts recommend the unselected patients with IAL into 3 classes with a different expected PAL and different indications for treatment: class I with mild IAL, where we expect a postoperative AL of a few hours, class II with moderate IAL and expectation of 5.04 ± 3.63 days and class III with severe IAL and expectation of a median of 15 days.

An aggressive and early approach to PAL is recommended in case of sudden start or increase of a large postoperative AL (>400 ml/min) in a patient with previous absent or minimal AL. There was no consensus on the choice of treatment of PAL, and these data reflect the lack of evidence-based guidelines.

Limitations

This paper presents several limitations. A limitation inherent due to the employed methodology is related to a possible poor response rate [21]. Nevertheless, a high response rate was achieved in this study since all the selected experts who started the first Delphi

Table 2: Summary table of recommendations

Topic	Statement	Score (%)	Clinical practice
Definition of PAL	PAL is defined as an air leak lasting longer than 5 days	87	*Recommended*
Preoperative assessment of risk factors for PAL	Predictive PAL risk scores preoperatively are not used	87	*Recommended*
	The predictive PAL risk scores are sometimes reliable and valuable	68	
Intraoperative detection and quantification of intraoperative alveolar air leak	Routine use of the bubbling test after completing a VATS anatomical resection	65	
	Selective use of MVT after completing a VATS anatomical resection	83	*Recommended*
Intraoperative classification of intraoperative alveolar air leak	An intraoperative alveolar air leak of <100 ml/min at the MVT should be classified as mild and self-limiting	81	*Recommended*
	An intraoperative alveolar air leak of 100–400 ml/min at the MVT should be classified as moderate	71	
	An intraoperative alveolar air leak of >400 ml/min at the MVT should be classified as severe	74	
Intraoperative treatment of intraoperative alveolar air leak	In the case of positive bubbling test, the treatment of intraoperative alveolar air leak is indicated only in high-risk patients	68	
	Mild intraoperative alveolar air leak should not be treated	61	
	Moderate intraoperative alveolar air leak in high-risk patients for PAL should be treated	90	*Recommended*
	Severe intraoperative alveolar air leak should be treated	90	*Recommended*
	After anatomic thoracotomy resection, experts prefer the parenchymal suture	81	*Recommended*
	After minimally invasive anatomic resection, experts prefer the use of sealants	55	
	In high-risk patients, the selective use of sealants beside and next to the suture line in the presence of intraoperative alveolar air leak	74	
Chest tube management	The use of a single 24 Fr	58	
	The use of a digital drainage system	61	
	There is currently sufficient evidence in the literature to support the use of digital drainage systems	52	
	In the immediate postoperative period, in the presence of a well-expanded residual lung, water seal is indicated only in the absence of AL	56	
	In the immediate postoperative period, in the presence of pneumothorax, moderate suction is indicated in the absence of postoperative AL	56	
	In the immediate postoperative period, in the presence of pneumothorax, moderate suction is indicated in the presence of mild postoperative AL	52	
	In the immediate postoperative period, in the presence of pneumothorax, moderate suction is indicated in the presence of moderate postoperative AL	65	
	In the immediate postoperative period, in the presence of pneumothorax, moderate suction is indicated in the presence of severe postoperative AL	68	
	The absence of air leaks is requested for chest tube removal	65	
	If there is too much fluid output to remove drainage, discharge the patient with a chest tube	68	
	If there is too much AL to remove drainage, discharge the patient with a chest tube	52	
Postoperative management of PAL	An aggressive and early approach to PAL is indicated in case of sudden start or increase of a severe postoperative AL (>400 ml/min) in a patient with previously no or minimal air leak	65	

Defined consensus statements and corresponding level of recommendation and score. Clinical practice was recommended if >75% of the experts reached an agreement.

AL: air leak; MVT: mechanical ventilation test; PAL: prolonged air leak.

round completed all remaining rounds of the Delphi. The effective use of reminder emails may have also contributed to the follow-up of the experts. Another limitation is a Consensus Group on PAL based on the individual experiences of skilled experts. The consensus is directed at the general thoracic surgical community, where the indications for the management of PAL may also differ based on the surgeon's skills. Conclusions of the Delphi would have been more representative of the variability if it had included more options or the answer had been open (e.g. the responder could indicate the number of days of AL at his discretion). However, the strength of Delphi depends on the participating experts. In the Delphi methodology, experts' votes were uniformly weighted. The experts were also blinded to the subjective opinions to reduce peer pressure from influential experts, granting optimal utilization of mutual knowledge, also providing the change of opinion of the experts considering the feedback of results from previous rounds. The last limitation is the potential selection bias assembling a group of experts with the same interests and opinions. As a result of this, the conclusions should be taken cautiously.

CONCLUSIONS

According to Delphi Survey, PALAS expert consensus working group reached an agreement on the majority of issues regarding

the detection and management of IAL and PAL. In the absence of prospective, randomized evidence supporting most of these clinical decisions, this document may serve as a guideline to reduce practice variation.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

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Conflict of interest: Alessandro Brunelli—advisory board and consultancy fee with Astra Zeneca, BD, Ethicon and Medtronic; Tim Batchelor—honoraria from Medela, Medtronic, J&J, BD, AstraZeneca and Bristol Myers Squibb; Thomas D'Amico—Scanlan Instruments: consultant, Medtronic: consultant; Isabelle Opitz—Roche, institutional grant and speakers bureau; AstraZeneca, advisory board and speakers bureau (2021); MSD, advisory board; Medtronic, institutional grant; René Horsleben Petersen—speaker fee from Medtronic and AMBU and advisory board member AstraZeneca, Roche and MSD. Other authors have no conflict of interest to declare.

Data Availability Statement

The data underlying this article will be shared on reasonable request to the corresponding author.

Author contributions

Francesco Zaraca: Conceptualization; Formal analysis; Supervision; Writing—original draft; Writing—review & editing. **Alessandro Brunelli:** Conceptualization; Methodology; Writing—review & editing. **Marco Damiano Pipitone:** Conceptualization; Writing—original draft; Writing—review & editing. **Amr Abdellateef:** Investigation; Writing—review & editing. **Firas Abu Akar:** Data curation; Writing—review & editing. **Florian Augustin:** Data curation; Writing—review & editing. **Tim Batchelor:** Conceptualization; Data curation; Writing—review & editing. **Alessandro Bertani:** Data curation; Writing—review & editing. **Roberto Crisci:** Conceptualization; Data curation; Writing—review & editing. **Thomas D'Amico:** Conceptualization; Data curation; Writing—review & editing. **Xavier Benoit D'Journo:** Data curation; Writing—review & editing. **Andrea Droghetti:** Data curation; Writing—review & editing. **Wentao Fang:** Conceptualization; Data curation; Writing—review & editing. **Alessandro Gonfiotti:** Data curation; Writing—review & editing. **Miroslav Janík:** Data curation; Writing—review & editing. **Marcelo Jiménez:** Data curation; Writing—review & editing. **Andreas Kirschbaum:** Data curation; Writing—review & editing. **Marko Kostic:** Data curation; Writing—review & editing. **Richard Lazzaro:** Data curation; Writing—review & editing. **Marco Lucchi:** Conceptualization; Data curation; Writing—review & editing. **Alessandro Marra:** Data curation; Writing—review & editing. **Sudish Murthy:** Data curation; Writing—review & editing. **Calvin S.H. Ng:** Data curation; Writing—review & editing. **Dania Nachira:** Data curation; Writing—review & editing. **Alessandro Pardolesi:** Data curation; Writing—review & editing. **Reinhold Perkmann:** Data curation; Writing—review & editing. **René Horsleben Petersen:** Data curation; Writing—review & editing. **Vadim Pischik:** Data curation; Writing—review & editing. **Michele Dario Russo:** Data curation; Writing—review & editing. **Isabelle Opitz:** Data curation; Writing—review & editing. **Lorenzo Spaggiari:** Data curation; Writing—review & editing. **Paula A. Ugalde:** Data curation; Writing—review & editing. **Fernando Vannucci:** Data curation; Writing—review & editing. **Giulia Veronesi:** Data curation; Writing—review & editing. **Luca Bertolaccini:** Conceptualization; Formal analysis; Supervision; Writing—original draft; Writing—review & editing.

Reviewer information

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