The Egyptian Journal of Bronchology

RESEARCH Open Access

Intracavitary anaesthesia for medical thoracoscopy procedural pain: the CAMP randomised trial

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Abstract

Background: Medical thoracoscopy (MT) under conscious sedation can be a painful procedure. A pilot study reported reduction in procedural pain with lidocaine application via chest tube before procedure. This study aimed at assessing the extent of effect of intrapleural lidocaine on pain during MT in a double-blind randomised trial.

Results: Thirty patients (mean age 48.3 years) were recruited, 14 randomised to the lidocaine group and 16 to the saline group. In four patients (two from each group), chest tube insertion prior to MT failed, and they were excluded from the final analysis. The mean (SD) visual analogue scale (VAS) pain score during procedure was 49 ± 33.2 for the lidocaine group and 57.4 ± 27.6 for the control group (mean difference − 8.4 points, $p = 0.49$). The VAS pain score as assessed by operator was 45.6 ± 19.8 for the lidocaine group and 46.6 ± 29.8 for the control group ($p = 0.97$). There was no difference in the VAS pain score at 120 min post MT or in the doses of sedatives used during procedure between the study groups.

Conclusion: ICA for MT does not seem to improve procedural pain as suggested by previous studies.

Trial registration: The study has been registered with the Pan African Clinical Trial Registry (PACTR202008762D15 9889).

Keywords: Medical thoracoscopy, Pleural disease, Anaesthesia, Interventional pulmonology

Background

Medical thoracoscopy (MT) has an important role in the diagnostic pathways of exudative pleural effusions with a diagnostic sensitivity of more than 90% [1]. It can act as a means of conducting pleurodesis thus combining diagnostic and therapeutic roles [2]. Typically, MT is performed via a single port and performed by respiratory physicians on spontaneously breathing patients under conscious sedation [3]. Analgosedation is attained by a combination of a benzodiazepine and an opiate [4, 5], but some centres replace benzodiazepines with propofol to benefit from the deeper sedation of the latter [6]. The procedure is generally tolerated, but some patients suffer from considerable pain during pleural biopsies or pleurodesis [7].

Intrapleural blockade, a technique that involves injecting an anaesthetic substance into the thoracic cage between the parietal and visceral pleura to produce ipsilateral somatic block of multiple thoracic dermatomes, has been described as a potent option to control postoperative pain [8] and nonsurgical pain from the chest and upper abdomen [9, 10]. This method is used by respiratory physicians prior to bedside chemical pleurodesis to reduce pain associated with the procedure [2].

A recent open-label pilot study has shown the safety of using intrapleural lidocaine as the main analgesic during MT with acceptable patient tolerability [11]. This trial aims to establish whether intrapleural lidocaine leads to lower pain scores during MT and whether this

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could be achieved with lower doses of intravenous analgosedation.

Methods

This study was a clinical trial that recruited patients admitted for MT at a single tertiary hospital. The study was approved by the Ethics Committee in Alexandria Medical School (REF 0106378), and all participants provided written informed consent. The study protocol is registered at the Pan African Clinical Trial Registry (PACTR202008762159889). The study adheres to the CONSORT guidelines.

Successive patients admitted for MT were approached if they were aged ≥ 18 years and have pleural effusion (pneumothorax induction not required). Patients with advanced renal or hepatic disease (where sedation is not deemed safe), complex septated pleural space on ultrasound, or substantial chest pain were excluded.

CAMP was a double-blind randomised placebo-controlled trial comparing intracavitary instillation of lidocaine (study medication) to normal saline (placebo). Participants were randomised in a 1:1 ratio to either groups using a blocked randomisation list generated using the Sealed Envelope online platform prior to study start. The study medication or placebo were prepared and administered by the only member of the team who had access to the randomisation sequence and was unblinded to treatment allocation. This member was not involved in other study assessments.

A 26F chest tube was inserted near the mid-axillary line prior to MT (minimum 1 h but up to 24 h) to allow drainage of most of the pleural effusion, with a maximum drainage rate of 1 l every 30 min. Ultrasound was used before procedure to confirm sufficient drainage. Prior to starting MT, 3 mg/kg lidocaine with a maximum dose of 200 mg mixed with normal saline to make up 20 ml (active arm) or 20 ml of normal saline (placebo arm) were injected into the chest tube followed by a 10-ml normal saline flush. The tube was then clamped, and the patient was asked to lie in the supine position. After 5 min, 200 ml of air was injected into the tube which was then clamped, and the patient was placed in lateral decubitus position. One to two milligrams of midazolam and 10–20 mcg of fentanyl (depending on patient weight, renal function and blood pressure) were given intravenously; the chest tube was removed, and the edges of the wound were infiltrated by 10 ml of 1% lidocaine. MT was subsequently carried out according to the local protocols including—if indicated—thoracoscopic pleurodesis. The same rigid thoracoscopy set (with 9-mm telescope) was used in all patients.

Further doses of analgosedation were allowed according to the discretion of the thoracoscopist who was blinded to treatment allocation.

A 100-mm visual analogue scale (VAS) was used to assess chest pain before MT and within 20 min of MT termination to describe pain during procedure (primary outcome). Another VAS score after 120 min of MT was completed (secondary outcome). Other secondary outcomes included the following: difference in VAS score from baseline to pain score during MT, (blinded) operator-rated VAS score for procedure discomfort, total doses of midazolam, and fentanyl used.

Based on pilot data [11], the mean difference in VAS score between groups was estimated to be 25 mm and the standard deviation of the control group 20 mm. For a study power of 0.9 and a significance level of 0.05, the sample size was 28 participants (14 per arm).

Comparison of normally distributed variables was done using independent *T* test. Mann-Whitney test was used for comparison if normality was not fulfilled. Comparison between rates was done using Fisher exact test. A per protocol analysis was carried out for all analyses.

Results

Between 24 August 2020 and 20 February 2021, thirty patients were recruited, 14 randomised to the lidocaine group and 16 to the saline group. In four patients (two from each group), chest tube insertion prior to MT failed, and they were excluded from the final analysis. Table 1 summarises the baseline and procedural data for the 26 patients included in the analysis. The two groups were matched in age, baseline VAS score, and details of MT, but there were more females in the lidocaine group than in the saline group. Regarding the primary outcome, the VAS score for pain during MT was not different between the treatment groups. None of the other secondary outcomes showed significant differences between the treatment groups (Table 1).

Discussion

The results of this trial do not support the routine use of intrapleural anaesthesia prior to MT due to lack of clinically meaningful reduction in pain scores.

Intrapleural spraying of lidocaine via semi-rigid thoracoscopy [7] or intercostal nerve block before rigid thoracoscopy [12] have been proposed to overcome substantial pain during MT. In addition, an open-label study which employed a method of anaesthesia similar to the current study for MT reported positive results [11]. However, given the observational or open-label nature of these studies, bias cannot be excluded. The robust design of the current study including blinding of the interventions means that the lack of effect is likely genuine.

An explanation for the lack of benefit from intrapleural anaesthesia in this study is that a substantial proportion of the discomfort from the procedure comes

Table 1 Baseline characteristics, procedural details, and study outcomes in the treatment groups of the study

Variable	Lidocaine group (n = 12)	Saline group (n = 14)	Treatment effect (95% CI)	Significance
Age[a] years	47.7 ± 18.5	49.8 ± 12		0.748
Sex[b], females	10 (83.3%)	6 (42.8%)		0.051
VAS baseline[c] mm	50 [4.3–60]	27.5 [10–62.5]		0.776
Effusion volume drained pre-MT[c] ml	1800 [1275–2475]	1800 [1275–2450]		0.938
Duration of chest tube in situ[c] minutes	115 [74–147]	75 [56–187]		0.471
Duration of MT[a] minutes	30 ± 12.2	29 ± 10.9		0.813
Effusion volume drained during MT[c] ml	25 [0–100]	50 [0–325]		0.474
Pleural nodularity at MT[b]	9 (75%)	6 (42.8%)		0.130
Pleurodesis performed[b]	7 (58.3%)	6 (42.8%)		0.695
Diagnosis[b]				0.652
· Inflammatory	2 (16.7%)	4 (28.6%)		
· Malignancy	10 (83.3%)	10 (71.4%)		
Number of pleural biopsies[c]	4 [3.25–5.75]	4 [3.74–4]		0.537
VAS during MT[a] mm	49 ± 33.2	57.4 ± 27.6	− 8.4 (− 33 to 16.2)	0.487
Change in VAS from baseline[a] mm	8.4 ± 29.6	21.1 ± 42.1	− 12.6 (− 42.6 to 17.3)	0.392
VAS 120 min post MT[a] mm	43.5 + 28.3	42.5 + 33.7	1.0 (− 24.4 to 26.4)	0.936
VAS operator-rated score[a] mm	45.6 ± 19.8	46.6 ± 29.8	− 1.1 (− 21.9 to 19.8)	0.971
Midazolam dose[a] mg	2.3 + 1.2	2.6 + 1.2	− 0.3 (− 1.3 to 0.6)	0.514
Fentanyl dose[a] mcg	35 + 16.7	35.7 + 16	− 0.7 (− 14.1 to 12.7)	0.913

CI, confidence interval; MT, medical thoracoscopy; VAS, visual analogue scale score on 100 mm scale
[a]Variables are summarised as mean ± standard deviation, and groups are compared using independent *T* test
[b]Variables are summarised as number and percentages, and groups are compared using Fisher's exact test
[c]Variables are summarised as median [interquartile range], and groups are compared using Mann-Whitney test

from the pressure of the trocar on the intercostal nerves during manipulation, and this type of pain cannot be alleviated with anaesthetising the pleura. A study limitation was the relatively large trocar (10 mm) used in this study which may have masked the efficacy of the intervention. Trialling intrapleural anaesthesia with the use of small MT sets (e.g. with 6 mm rigid scopes or semi-rigid scopes) may be warranted. Another limitation is that the lidocaine group had a higher percentage of female patients. The theoretical differences in pain threshold between sexes could have contributed to obscuring any possible treatment effect of lidocaine.

Conclusions

In conclusion, this randomised trial showed that the use intrapleural anaesthesia before MT did not lead to better tolerability of the procedure or reduce the need for intravenous sedatives.

Abbreviations

CAMP: Cavitary anaesthesia for medical thoracoscopy procedure; MT: Medical thoracoscopy; VAS: Visual analogue scale

Acknowledgements

Not applicable

Authors' contributions

AMA shared in creation of the research idea and shared in writing the paper. MG shared in creation of the research idea and in doing the procedures. MS reviewed the research idea. SM reviewed the research idea. MH wrote most of the paper and shared in doing the procedures. The authors read and approved the final manuscript.

Funding

All the procedures were done using Alexandria medicine faculty without any impact of this on the design of the study or collection, analysis, and interpretation of data.

Availability of data and materials

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

Declarations

Ethics approval and consent to participate

The Alexandria medicine faculty ethics committee (IRB NO: 00012098- FWA NO: 00018699) approved this research with the serial number 0106378. A written informed consent was taken from each patient.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

Received: 18 June 2021 Accepted: 10 September 2021
Published online: 28 September 2021

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