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Cryoablation of the intercostal nerve after mini-thoracotomy procedures: Pilot prospective interventional clinical study

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ABSTRACT

Background: Minimally invasive surgical procedures are a current trend in cardiac surgery. The advantage is minimal surgical trauma, reduced probability of adhesion formation, and a smaller surgical scar. During these procedures, the incidence of damaging the intercostal nerve and a subsequent increased perception of postoperative pain. *Methods*: One of the options in anesthesiological interventions is cryoablation of the intercostal nerve. In this pilot study, we compared two groups of patients. Group A (3 patients), with cryoablation performed, and Group B, the control group of 7 patients, treated according to the current analgesic protocol at our department. *Conclusion*: Compared with Group B, from admission, we recorded a decreased intensity of pain and a lower consumption of opioid analgesics in Group A.

Keywords: Analgesics, cryoablation, intercostal nerve, pain, surgical procedure

1. INTRODUCTION

Sternotomy incision is a standard in cardiac surgery. Due to its sophisticated technical execution, perioperative and postoperative management has been well-established within cardiac surgery. Anesthesia management, adjustment of artificial lung ventilation during surgery, and elaboration of postoperative protocols for postoperative pain management was adapted to the surgical procedures performed via sternotomy (Balaguer et al., 2012). Since the mid-1990s, new minimally invasive approaches have begun performed in cardiac surgery. The first minimally invasive operations were performed on the aortic valve guided through a parasternal incision in the third intercostal space (Jahangiri et al., 2019). These followed by procedures on the mitral valve and surgical revascularizations of the myocardium (Ram et al., 2021).

The prominent pioneers in this field were FJ Benetti and H Vanermen. After the year 2000, we have seen a boom in minimally invasive surgery (MICS) using access ports. This technique has proven its safety and feasibility worldwide, providing reduced surgical trauma, fewer postoperative

complications, a shorter rehabilitation period, and greater comfort and aesthetic appearance for the patient (Onan, 2020). These approaches provide significant benefits to patients with underlying comorbidities such as advanced age, renal insufficiency, obstructive lung disease, or neurological disease (Onan, 2020). However, not every patient is a candidate for MICS. Therefore, indication workshops should evaluate whether invasive surgery represents an alternative option.

One of the complications of MICS in postoperative care is postoperative pain control. A minimally invasive incision is associated with a higher risk of intercostal nerve damage in the given intercostal space in which the incision and the retractor was placed, with consequent higher pain intensity in the postoperative period and higher consumption of opioid analgesics (Cavaleri et al., 2021; Torre et al., 2022). The regional anaesthetic techniques for intense pain management such as fascial blocks, namely "Erector Spinae Plane Block" (ESPB) and "Pectoralis and Serratus Plane Nerve Blocks" (PECS I and PECS II) are advantageous. A promising analgesic method is the interosseous nerve cryoablation technique performed in the perioperative period. In this article, we compare the pain intensity in two groups of patients who underwent minimally invasive cardiac surgery.

2. METHODS

The pilot study included ten patients aged (48 min-65 max) 52 median years who underwent mini-thoracotomy. The study was approved by the hospital ethics committee under number 1/2019/VUSCH/EK and registered at clinicaltrials.gov under number NCT03915301. The inclusion criteria were a minimally invasive cardiac surgery procedure via mini-thoracotomy using extracorporeal circulation and patient consent to the anesthetic technique before surgery. The exclusion criteria were pre-existing diseases: Type I and II diabetes mellitus, nephropathy, systemic disease, and neurological disease.

Table 1 The performed cardiac surgery in group A and B. MIDCAB - Minimally Invasive Direct Coronary Artery Bypass Grafting, ASD - Atrial Septal Defect.

Procedure	Group A (Cryo)	Group B (Control)
MIDCAB	1	1
Mitral valve plasty	1	1
Mitral valve replacement	1	2
ASD closure	0	1
Tricuspid valve plasty	0	1
Left atrium myxoma	0	1

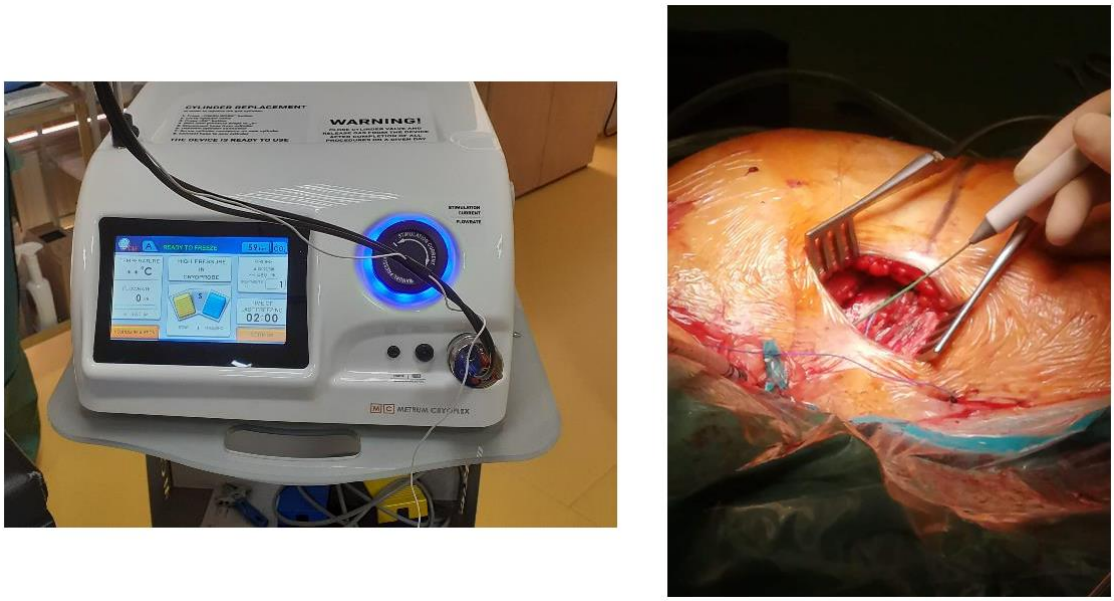

Figure 1 Cryogenerator (Cryo-painless) – right, and cryoprobe during the mini-thoracotomy procedure - left.

The three patients from Group A 3 underwent cryoablation of the interosseous nerve in the perioperative period in 2 cycles (2 minutes cryo -78st, 30s defrost and again 2 minutes cryo -78st, 20s defrost) with the Cryo-painless device, where the cooling medium was carbon dioxide (Table 1, 2). Cryoablation (Figure 1) performed an anaesthesiologist before the end of the operation. Patients from Group B received standard postoperative analgesic pharmacotherapy according to the approved analgesic protocol. The monitored parameters were analgesic consumption and pain intensity measured on a numerical pain scale (0-10) where "0" represents the lowest pain intensity and "10" is the most vigorous pain intensity the patient can imagine.

Table 2 Standard analgesic protocol at the Clinic of anesthesia and intensive care.

Day of surgery	Morphine 20mg/20ml (12-24h) (2-4ml/h) Analgin 2.5g/8h i.v. / Paracetamol 1g/8h i.v. Severe pain: Morphine 1% bolus, Metamizol/Paracetamol adjunctive treatment Modification of drains? Fascial muscle blockade ESPB, PECS II
1. Postoperative day	Analgin 2.5g /8h i.v + Tramal 100mg/8h i.v Pain VAS ≥ 7 Nalbufin, Pethidine, Fascial muscle blockade ESPB, PECS II
2. Postoperative day	Novalgin (metamizol) 500mg /8h i.v or p.o, VAS < 3 Dual-combination analgesics VAS ≥ 3 Pain VAS ≥ 7 Nalbufin, Pethidine, Fascial muscle blockade ESPB, PECS II

3. RESULTS

Patients in group A after cryoablation had constant pain max VAS 1 (Figure 2) and did not require additional bolus application of analgesics (Table 3). In control group B, we observed frequent repeated bolus administration of analgesics as well as higher consumption of non-opioid and opioid analgesics, and also repeated application of regional blocks.

Table 3 Average daily analgesics consumption of patients in groups A and B. ESPB - Erector Spinae Plane Block, PECS - Pectoralis and Serratus Plane Nerve Blocks, POD – postoperative day.

	0 POD		1 POD		2 POD		3 POD		4 POD		5 POD	
Group	A	B	A	B	A	B	A	B	A	B	A	B
Morphine/mg	15	35	0	0	0	0	0	0	0	0	0	0
Petidin/mg	0	0	0	33	0	23	0	10	0	10	0	0
Nalbufin/mg	0	0	0	6,7	0	5, 3	0	4	0	4	0	0
Tramadol/mg	0	0	300	300	50	28, 8	37,5	20,4	0	37, 5	0	37, 5
Paracetamol/g	2	2	3	1, 8	0	1, 7	0	1, 7	0	1,1	0	1, 3
Metamizole/g	7, 5	7, 5	7, 5	7, 5	1, 5	2, 5	1, 5	0, 7	1, 5	1, 1	1, 5	1, 3
NSAI/mg	0	0	0	0	0	10	0	0	0	10	0	0
ESPB/PECSII	(-)	(+)	(-)	(+)	(-)	(+)	(-)	(-)	(-)	(-)	(-)	(-)

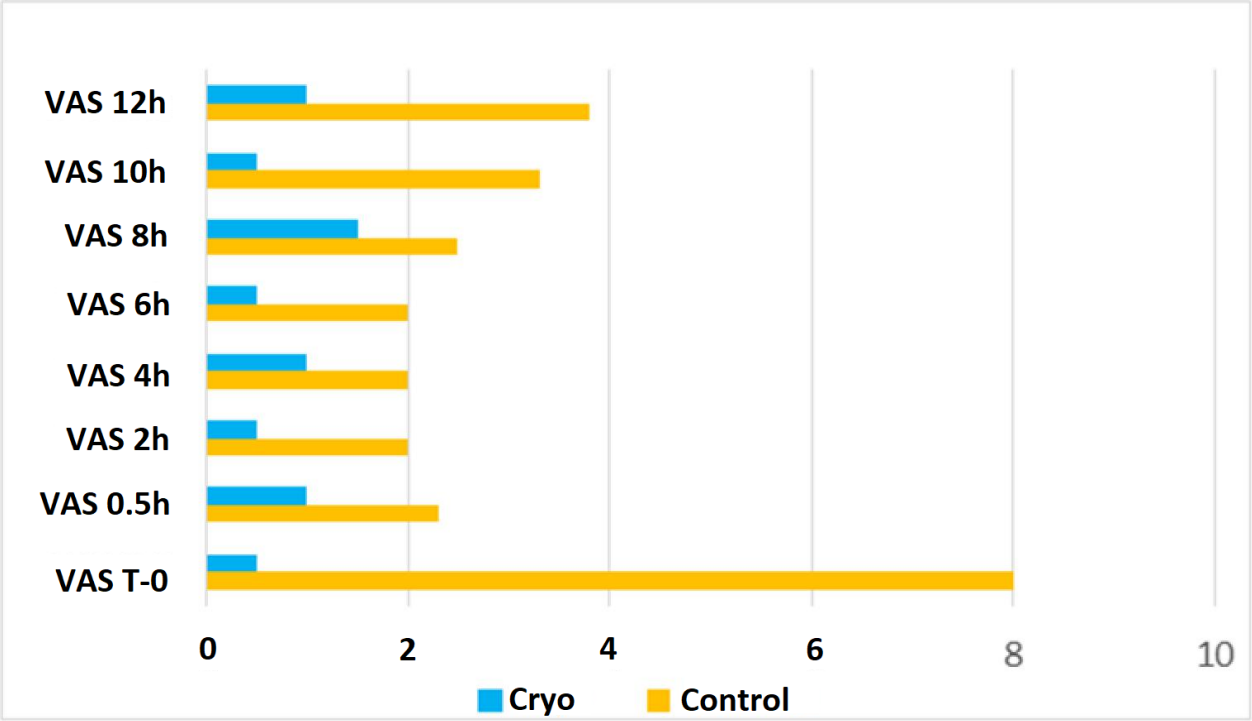

Figure 2 Mean value of change in pain intensity (VAS) 0-12 hours after admission from the operating room.

4. DISCUSSION

One of the complications of MICS in postoperative care is postoperative pain control. A minimally invasive incision is associated with a higher risk of intercostal nerve damage in a given intercostal space with guided incision and the retractor placed. Patients more frequently require intermittent administration of opioid analgesics and, or application of regional blocks. A VAS value < 3 is considered sufficient analgesia. The benefit of regional fascial blockades (ESPB and PESC II) in non-cardiac surgery was confirmed by other papers that have followed postoperative pain in patients after lung resection or chest wall surgery or mastectomies (Cavaleri et al., 2021; Torre et al., 2022). In the first group of patients, an innovative cryoablation method was used. This technique is classified as a minimally invasive therapeutic method.

It is based on temporary interruption of the sensory innervation of vulnerable nerve structures of the nervous system by application of low temperature (Kočan et al., 2022). In the studied group B, the standard essential analgesia was applied according to the analgesic protocol of our department. Still, the patients did not require any intermittent dose of analgesics (paracetamol, NSAIs or opiates). The principle of the method is the formation of ice crystals by a cryoprobe connected to a cryogenerator, which disrupt the myelin parts of the nerve sheath without interrupting the nerve itself (Chen et al., 2015). The nerve itself continues to have the ability to regenerate after the procedure. The advantage of ablation is the absence of the formation of a postoperative neuroma, which is a frequent complication after surgical incisions.

The principle of cryoanalgesia is based on the pathophysiology of nerve damage – axonotmesis. It is the disruption of the nerve by the so-called Wallerian degeneration, which occurs in the proximal part of the axon lesion. The damage involves the axon and myelin sheath, but the Schwann cells, endoneurium, and epineurium remain intact. The regeneration rate of the damaged nerve by cryoanalgesia is 1mm per day. From clinical studies, the lasting effect of cryoanalgesia is assumed to be 6-12 months (Kočan et al., 2022). Patients who experience pain of moderate to severe intensity VAS ≥5 are best suited for cryoablation when the benefit of this method is most pronounced. Another advantage of cryo-analgesia is the variability of its use within the perioperative or postoperative period.

5. CONCLUSION

Minimally invasive operations in cardiac surgery bring a set of benefits to patients, but their application requires the management of acute intense pain in the postoperative period. In addition to temporary regional fascial blocks, a new innovative method -

intercostal nerve cryoablation, appears to be promising. We present the pilot data indicating a reduction in analgesic consumption as well as better pain control in the postoperative period with the use of the cryoablation technique.

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Author contribution

KL, RR contributed to the conception and study design. Data collection by KL, RR, RS, VJ, VJ were performed. Analysis and evaluation of data were performed by KL, RR, RS, VJ. The first draft of the manuscript was written by KL, VJ and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethical approval

The study was approved by the hospital ethics committee no. 1/2019/VUSCH/EK.

Informed consent

Written and oral informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants for whom identifying information is included in this manuscript.

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Conflict of interest

The authors declare that there is no conflict of interests.

Data and materials availability

All data sets collected during this study are available upon reasonable request from the corresponding author.

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