

## Epidrum<sup>®</sup>: a new device to identify the epidural space with an epidural Tuohy needle

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**Abstract** Epidrum<sup>®</sup> is an optimal pressure, loss of resistance device for identifying the epidural space. We investigated the usefulness of Epidrum versus the loss of resistance or hanging drop techniques while performing epidural anesthesia. Eighty adult patients who were scheduled for elective surgery under lumbar epidural anesthesia were randomized into two groups. The first group (Epidrum group) consisted of 40 adult patients who were scheduled for epidural anesthesia using Epidrum. The second group (control group) consisted of 40 adult patients who were scheduled for epidural anesthesia using the loss of resistance or hanging drop technique. We recorded the time required to identify the epidural space and outcomes of epidural catheterization. The attending anesthesiologists were also questioned regarding the ease of control of the Tuohy needle and of epidural space identification with each method. The time required to perform epidural anesthesia was significantly shorter in the Epidrum group than in the control group [28 s (10–76) vs. 90 s (34–185); median (interquartile range)] ( $p < 0.05$ ). Tuohy needle control was significantly easier in the Epidrum group than in the control group ( $p < 0.05$ ). Epidrum is useful for performing epidural anesthesia quickly while obtaining good Tuohy needle control.

**Keywords** Epidural space · Tuohy needle · Epidrum<sup>®</sup>

### Introduction

Anesthesiologists have routinely identified the epidural space by the loss of resistance or hanging drop techniques while performing epidural anesthesia [1]. However, a clear loss of resistance cannot be felt in patients with ligamentum flavum weakness [2]. Furthermore, the hanging drop technique might be regarded as an illogical choice for identifying the lumbar epidural space because of the absence of a true negative pressure in this region [3]. Epidrum<sup>®</sup> (Exmoor Innovations Ltd., Somerset, UK) is an optimal, constant, low-pressure, loss of resistance device for identifying the epidural space. Interposed between the Tuohy needle and syringe (Fig. 1a), the device is charged with air to expand its diaphragm (Fig. 1b). When the Tuohy needle is advanced, sudden collapse of the diaphragm signals the needle's penetration into the epidural space (Fig. 1c). We investigated the usefulness of Epidrum compared with the conventional loss of resistance or hanging drop techniques while performing epidural anesthesia.

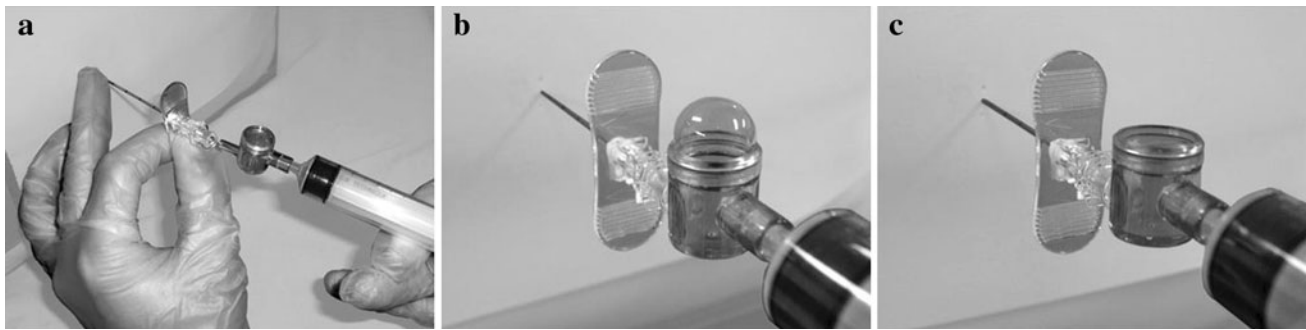
This open, single-center trial was approved by the Internal Review Board of Sapporo Medical University Hospital (Sapporo, Japan), and written informed consent was obtained from each patient. We studied 80 adult patients [American Society of Anesthesiologists (ASA) physical status I or II, between 22 and 86 years of age] who were scheduled for elective surgery under lumbar epidural anesthesia, in a randomized, single-blind, controlled clinical trial by the envelope technique. Patients with lumbar spinal disease, known coagulation disorders, or severe obesity (body mass index  $>35 \text{ kg/m}^2$ ) were excluded. All data were collected by an independent unblinded observer.

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**Fig. 1** Appearance of Epidrum<sup>®</sup>. Interposed between the Tuohy needle and syringe (a), the device is charged with air to expand its diaphragm (b). When the Tuohy needle is advanced, sudden collapse

of the diaphragm gives a positive visual signal that the needle has penetrated the epidural space (c)

Patients were randomized into two groups: a group to receive epidural anesthesia using Epidrum ( $n = 40$ ) (Epidrum group) and a group to receive epidural anesthesia by the loss of resistance technique ( $n = 35$ ) in which the anesthesiologist continuously advanced the needle with constant pressure exerted on the plunger or the hanging drop technique ( $n = 5$ ) (control group). We measured and recorded the time taken to identify the epidural space and outcomes of epidural catheterization (success or failure, dural puncture). The time required to identify the epidural space was defined as the time from the first skin perforation until the needle's penetration into the epidural space, as evidenced by the attending anesthesiologist. Furthermore, the attending anesthesiologists were questioned regarding the ease of Tuohy needle control (1, easy; 2, moderate; 3, difficult) and certainty epidural space identification (1, certain; 2, moderately certain; 3, uncertain). Data of interval scales are expressed as mean  $\pm$  standard deviation (SD) and were analyzed by the unpaired  $t$  test when normally distributed. Data of ordinal scales are expressed as median with interquartile range (IQR) and were analyzed by the Mann–Whitney  $U$  test. We used GraphPad Prism software (Prism; La Jolla, CA, USA) to analyze these data. A probability value of  $<0.05$  was considered statistically significant.

Patients in both groups were similar in terms of gender, age, weight, and height (Table 1). There were no statistically significant differences between groups regarding outcomes of epidural catheterization and clinical effect of epidural anesthesia; however, there was one case of accidental dural puncture in the control group. The time required to identify the epidural space was significantly shorter in the Epidrum group (median 28 s, IQR 10–76) than in the control group (median 90 s, IQR 34–185) ( $p < 0.05$ , Fig. 2a). The Tuohy needle was significantly easier to control in the Epidrum group than in the control group ( $p < 0.05$ , Fig. 2b). There was no statistically significant difference between two groups in certainty of epidural space identification (Fig. 2c).

**Table 1** Patients' background

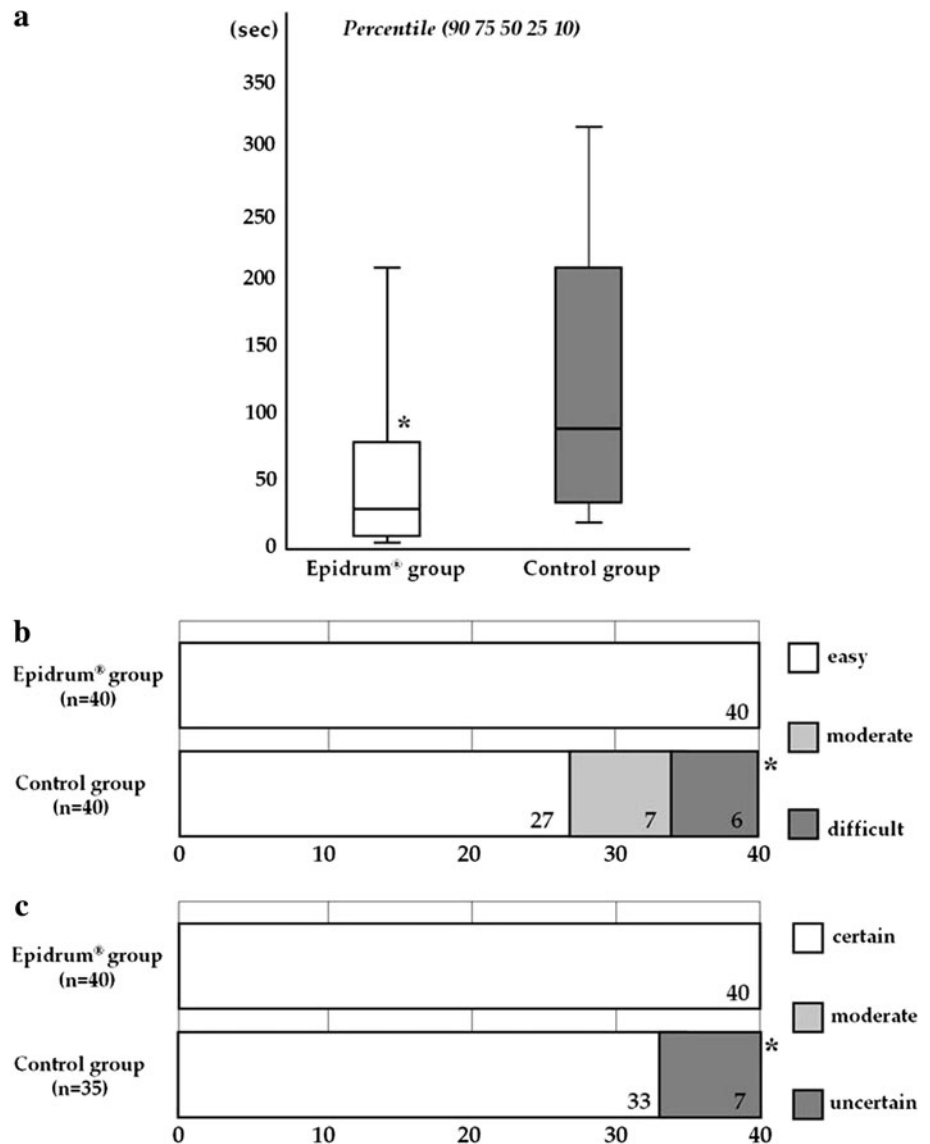
	Epidrum <sup>®</sup> group ( $n = 40$ )	Control group ( $n = 40$ )
Gender (female/ male)	25/15	24/16
Age (years)	54.3 $\pm$ 18.2	51.7 $\pm$ 15.9
Weight (kg)	55.7 $\pm$ 9.7	57.2 $\pm$ 11.0
Height (cm)	157.7 $\pm$ 8.0	159.3 $\pm$ 7.7
Level of epidural space ( $n/40$ )		
T11/12	10/40	11/40
T12/L1	25/40	21/40
L1/2	4/40	6/40
L2/3	1/40	2/40

Data expressed as mean  $\pm$  standard deviation or numbers. There were no statistically significant differences in these parameters between groups

## Discussion

Epidural anesthesia is a widely accepted technique associated with putative advantages for coagulation homeostasis and cardiovascular, respiratory, gastrointestinal, metabolic, and immune functions [4]. The loss of resistance technique is most frequently used to detect the epidural space [1]. This technique, however, is sometimes difficult to perform and may be accompanied by minor or major complications and may be time consuming. As the loss of resistance is a subjective feeling, higher failure rates occur with inexperienced anesthesiologists [5]. Several attempts have been made to improve or facilitate epidural space detection by the loss of resistance technique by adding a visual or an acoustic signal [2, 6, 7]. Despite the advantages claimed, none of these techniques have been widely used, probably because they offer no clear additional value or are too cumbersome. Of the attempts made to identify a suitable method that permits the use of both hands on the Tuohy needle, only the hanging drop method is worthy of imitation [1]. Whereas this technique allows

**Fig. 2** Main results of this study. Time required to identify the epidural space (a). Data expressed as median with interquartile range. Time required was significantly shorter in the Epidrum group than in the control group ( $*p < 0.05$ ). Ease of Tuohy needle control (b). Needle handling was significantly easier in the Epidrum group than in the control group ( $*p < 0.05$ ). Certainty of epidural space identification (c). There was no statistically significant difference between groups



more control in handling the Tuohy needle, it lacks reliability in the lumbar region [3].

In this study, we found that the use of Epidrum decreased the time required to accurately identify the epidural space compared with the loss of resistance or hanging drop techniques. The Epidrum enabled the anesthesiologist to control the Tuohy needle with both hands. Handling the Tuohy needle is thus improved, and passage through the ligamentum flavum can be better controlled. Although this is also true with the hanging drop technique, that technique lacks reliability in the lumbar vertebral region because the negative pressure in this region might be smaller than in the thoracic region [3]. With the loss of resistance technique, clear loss of resistance cannot be felt in patients with ligamentum flavum weakness. The use of Epidrum enabled handling of the Tuohy needle with both hands, and resistance by bony structures or the ligamentum flavum was

therefore easily recognized. As a result of this characteristic, all punctures obtained with the use of Epidrum were scored as certain. When observing resident doctors administering epidural anesthesia, it is sometimes difficult for the supervising anesthesiologist to determine whether there is true loss of resistance by simply watching the resident perform the procedure due to the varied pressure applied to the plunger. Visual observation of loss of resistance with Epidrum removes operator subjectivity and variability; thus, its use might offer a more precise end point compared with the standard glass syringe. There were no statistical differences between the two groups in outcomes of epidural catheterization and in clinical effect of epidural anesthesia. Epidrum clinically provided an effect of epidural anesthesia equivalent to that of the loss of resistance technique.

A limitation to this study is that because we could not blind the equipment per se, results might possibly have been

affected. However, we conclude that identifying the epidural space with the aid of Epidrum is reliable, simple, and safe. This new device offers several advantages over conventional epidural space identification techniques in terms of time required for successful detection, greater Tuohy needle stability, and safer resident anesthesiologist training.

**Conflict of interest** This research was supported solely by institutional and/or departmental sources. None of the authors have any financial interests in products related to this study.

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