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INSTRUMENT REVIEW

Pisat's Visual Vasopressor Injection Needle: A New Device for Increasing Patient Safety in Laparoscopic Myomectomy

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About the Reviewer

Dr. Sanket V. Pisat is a Gynaecological Endoscopic Surgeon in Mumbai, India. He completed his post-graduation from Grant medical college, Mumbai, and his endoscopy training from ETCA, Belgium. He is a member of the managing council of Mumbai Obstetric and Gynaecological Society. Dr Sanket Pisat has invented and patented a new instrument to increase patient safety in laparoscopic myomectomy called "Pisat's Visual Vasopressor Injection Needle" (VVIN). Patented in India and internationally, this concept is the first of its kind in the world. The instrument has been termed by the president of the ISGE (International Society for Gynaecological Endoscopy) to be a major progress in the laparoscopic treatment of fibroids, who has recommended its use to the international community.

Abstract

Introduction The use of vasopressin and other vasoconstrictive agents to reduce blood loss during laparoscopic myomectomy significantly reduces blood loss and operative time. However, serious cardiovascular complications following the use of intra-myometrial injection of vasopressin solution have also been reported. Most of these side effects are believed to be due to inadvertent intravascular injection of vasopressin solution.

Aims and Objectives To describe a new design of an injection needle, Pisat's Visual Vasopressor Injection Needle (VVIN), that can be used during laparoscopic myomectomy to minimise the incidence of an inadvertent intravascular injection of a vasoconstrictor solution.

Results A total of 53 patients who underwent laparoscopic myomectomy at various hospitals in Mumbai, India, were studied over a period of two years. Out of these, 23 patients were operated upon using a standard 5-mm laparoscopic injection needle, and 30 patients were operated upon by using a VVIN. Out of the 23 patients in whom a regular needle was used, four patients (17.39%) demonstrated a significant (over 20 percent of pre-injection value) but transient elevation in pulse and blood pressure readings at 1-min post-injection. This gradually returned to baseline at 10 min after the injection. None of the 30 patients in whom VVIN was used after confirming a negative aspiration

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demonstrated any significant change in post-injection pulse or blood pressure recordings.
Conclusions Using a VVIN during a laparoscopic myomectomy enables the surgeon to detect an inadvertent vascular puncture very early, even in a small calibre blood vessel, and with much more sensitivity than a regular needle. This increases patient safety during the intra-myometrial injection of a vasoconstrictive agent during myomectomy and reduces the incidence of catastrophic complications.

Keywords Laparoscopy · Myomectomy · Vasopressin · Fibroids · Laparoscopic myomectomy

Pisat's Visual Vasopressor Injection Needle (VVIN)

It is standard surgical practice to inject a diluted solution of a vasopressor agent into the fibroid to reduce blood loss during laparoscopic myomectomy [1]. Though several studies have demonstrated the safety of vasopressin, its use has also associated with intra operative haemodynamic fluctuations [2], and rarely life threatening side effects. These are mostly believed to be due to its inadvertent intravascular injection. In several countries, vasopressin has not been commercialized because of its potential adverse effect on cardiovascular system.

In laparoscopic surgery, the needle used for injecting vasopressin into the fibroid is about 33 cm long, and this needle is completely opaque in its entire length. Most vessels in the myoma capsule are thin-walled capillaries and small venous channels [3]. Even if the surgeon were to puncture a blood vessel within the myoma and aspirate, the blood column would not rise to a distance of 33 cm, high enough to stain the fluid in the syringe red.

In contrast, incorporating a small, transparent area (like a window) within the needle shaft, close to the tip of the needle, would give a much higher chance of seeing blood in this window when the surgeon aspirates with his syringe [4]. The needle can then immediately be withdrawn and repositioned. This remarkably reduces chances of inadvertent intravascular injection of vasopressin and increases patient safety.

Detailed Design of the VVIN

The VVIN is a 33-cm-long and 5-mm-wide hollow bore metallic instrument, quite similar to the 5-mm laparoscopic needle that is used for infiltrating vasoconstrictor solution during laparoscopic myomectomy. At the proximal end of the instrument, which remains outside the abdomen, is a hub that attaches to a standard disposable syringe. At the terminal end which is inserted into the abdomen, the VVIN has a detachable, disposable tip which can be fixed on to the shaft by a screw locking mechanism (Fig. 1).

The VVIN TIP

The disposable VVIN tip has a plastic hub and a terminal metallic needle tip. The plastic hub is transparent, 1 cm long, and has a hollow central cylinder measuring 2 mm in diameter. The lumen of this hollow cylinder is continuous with the lumen of a 2.5-cm-long metallic needle tip which is attached to the terminal end of the instrument. The detachable terminal portion makes the instrument easy to clean. This avoids the need and cost of a single use disposable instrument, as the metallic shaft can be sterilized and re-used.

Using the VVIN

The VVIN along with the disposable tip is first flushed with dilute vasopressin solution to remove the air column within the VVIN. The VVIN is then inserted through any standard 5 mm port into the abdominal cavity. A suitable site over the myoma is chosen as per the surgeon's preference and the VVIN inserted into the fibroid capsule, so as to lie in the sub-capsular plane. Using a 20-ml syringe, negative pressure is applied. If the tip of the needle has inadvertently punctured the lumen of a blood vessel, the cylindrical column within the plastic hub of the VVIN immediately shows a blood stained aspirate (Fig. 2). Alternatively, if the needle is not in a vessel lumen, the aspiration shows clear fluid and vasopressin can be safely injected.

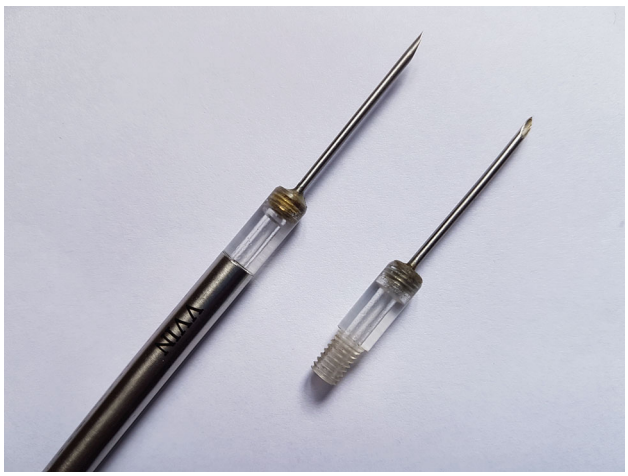

Fig. 1 The design of the VVIN with its detachable transparent hub

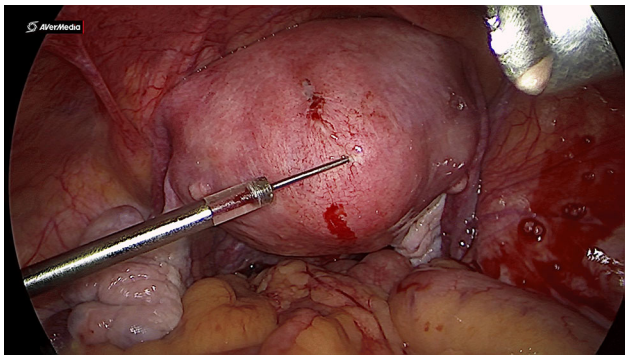

Fig. 2 Blood-stained aspirate seen within transparent needle hub indicating a vascular puncture

Using a VVIN, an aspirate volume of merely 0.03 ml of blood is sufficient to detect an intravascular puncture. This is lesser than one single drop of blood, and 27 times more sensitive than a regular myoma injection needle. A prospective randomised study published by Pisat and van Herendael [4] demonstrated significantly lesser haemodynamic fluctuations with the use of a VVIN as compared to a regular needle, with no adverse cardiovascular effects.

With litigations due to surgical complications increasing, video recording of laparoscopic surgeries has become common. Using a VVIN would provide documentary evidence to prove that the surgeon has taken adequate precaution to avoid an inadvertent intravascular injection.

A patent application for the device has been filed both in India (Application no 201721001762) and internationally. A thorough worldwide search of patent databases has confirmed that no such device exists, making this invention a worldwide first. More details, case studies and videos can be found online on www.pisatsvvin.com.

Compliance with Ethical Standards

Conflict of interest Dr Sanket Pisat declares that he has no conflict of interest.

References

1. Mettler L, Schollmeyer T, Tinelli A, et al. Complications of uterine fibroids and their management, surgical management of fibroids, laparoscopy and hysteroscopy versus hysterectomy, haemorrhage, adhesions, and complications. Obstet Gynecol Int. 2012;9:2012.
2. Song T, Kim MK, Kim ML, et al. Use of vasopressin vs epinephrine to reduce haemorrhage during myomectomy: a randomized controlled trial. Eur J Obstet Gynecol Reprod Biol. 2015;31(195):177–81.
3. Tinelli A. Uterine fibroid pseudocapsule: an update of its importance in fibroid management and female reproduction. Int J Gynecol Obstet Reprod Med Res. 2014;1(1):7–10.
4. Pisat S, van Herendael B. Pisat's visual vasopressor injection needle: an innovative tool for increasing patient safety in laparoscopic myomectomy. Surg Technol Int. 2017;9:30.