

The Almodin–Moron Trocar for Uterine Entry during Fetal Surgery

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Key Words

Hysterotomy · Fetal surgery · Open fetal surgery

Abstract

Objective: Compare the use of a newly designed and reusable metal trocar for initial uterine entry with the disposable Tulipan–Bruner trocar in creation of a hysterotomy for fetal surgery. **Methods:** Six consecutive patients undergoing hysterotomy for intrauterine repair of myelomeningocele were randomized to uterine entry either with the Tulipan–Bruner trocar or with the Almodin–Moron trocar. Blood loss was estimated by the primary surgeon. **Results:** There was no statistically significant difference in the uterine entry times between the trocars. Blood loss was estimated to be approximately the same. The Almodin–Moron trocar was judged to provide easy handling with good safety. **Conclusions:** The Almodin–Moron trocar provides a uterine entry during creation of a hysterotomy that is as quick and causes as little trauma as the Tulipan–Bruner trocar.

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Introduction

Open fetal surgery has been gaining ground not only as an important lifesaver procedure, but also in terms of providing the possibility of correction of conditions in the fetus that were considered too risky and ethically questionable in the past. The turning point started with the introduction of open fetal repair of the myelomeningocele, a condition that affects almost 2,000 infants every year in the United States alone [1], at the Vanderbilt University Medical Center in April 1997 [2]. Since then, the intrauterine repair of non-lethal malformations through a hysterotomy has become a therapeutic option and its increased occurrence has offered opportunities for improvements in surgical techniques and instrumentation, which has made this type of intervention a reality [3, 4].

After a first contact with the medical team at the Vanderbilt University Medical Center in 2002, a group of visiting medical doctors from the Fetal Medicine Department at the Federal University of São Paulo (UNIFESP) decided to bring the technique for myelomeningocele repair to Brazil. Following the same protocol as described by Tulipan and Bruner [2] and using the same surgical techniques and instrumentation, the first open fetal procedure for myelomeningocele repair was carried out in August 2003 in São Paulo University Hospital with great success.

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Among the instruments imported from the USA for the fetal open surgery is the Tulipan–Bruner trocar for uterine entry, a disposable device that has already been shown to be more efficient than the previous standard entry with electrocautery [4]. However, cost and bureaucracy problems to bring this instrument from the USA to Brazil have motivated the medical team to develop a new device.

The purpose of this report is, therefore, to describe a new three-piece reusable trocar made of metal designed by the authors to provide uterine entry during creation of a hysterotomy as an alternative for the originally imported disposable Tulipan–Bruner trocar.

Material and Methods

This work was approved by the Ethics Committee for Research and the protection of Human subjects of São Paulo Federal University (UNIFESP) in September 2003. Six consecutive patients were randomized for uterine entry with either the Tulipan–Bruner trocar (Cook Inc., Bloomington, Ind., USA) or the new Almodin–Moron trocar (Patent no. PI0402885–6, Ingamed Ltda, Brazil). After the patient had undergone induction of general anesthesia, the group coordinator randomly selected a sealed envelope from a box where they had been previously stored by another doctor, opened it and the trocar for uterine entry for the case was then assigned.

The Almodin–Moron trocar is a metal version of the Tulipan–Bruner trocar, which permits its sterilization and reuse. It is composed of a 44F aluminum central introducer 13.5 cm in length with a blunt tip that tapers for 2 cm to an inner lumen that will accept a 0.9 mm guidewire (fig. 1a), which we named 'entry introducer'. It also comprises a second aluminum introducer with an atraumatic tip 12 cm in length (fig. 1b), which we named 'clearing introducer', and a stainless steel sleeve 10.5 cm in length with a 14 mm wide slot that goes along its entire length, through which the stapling device can be introduced (fig. 1c).

Use of the Tulipan–Bruner trocar followed the protocol described in Bruner and Tulipan [4], which is basically the same used for the Almodin–Moron trocar. After the placement of the stay sutures, which were elevated by an assistant to provide counteraction, an 18-gauge Touhy needle was introduced into the amniotic cavity under direct ultrasonography (fig. 2a). A 1.5 mm guidewire was then inserted through the needle lumen, and the needle was removed (fig. 2b).

The tapered aluminum introducer together with the sleeve was passed over the guidewire and pushed through the uterine wall under direct ultrasonographic guidance (fig. 2c). Once correctly in place, the guidewire and the introducer were removed, and the amniotic fluid was collected through the metal sleeve in a sterile basin (fig. 2d). The atraumatic clearing introducer was then placed in the sleeve and with its help the sleeve was positioned close to the uterine wall, where the hysterotomy would be carried out (fig. 2e). The atraumatic introducer was removed and the footplate of the stapling device (U.S. Surgical Premium Poly CS-57; U.S. Surgical Corporation, Norwalk, Conn) was then introduced through the slot in the metal sleeve, and once it was correctly po-

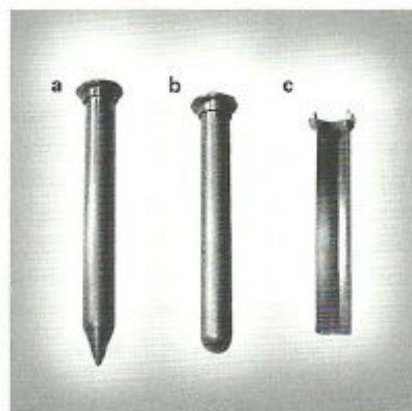


Fig. 1. Almodin–Moron trocar. Entry introducer (a), clearing introducer (b) and sleeve (c).

sitioned, the sleeve was removed and the stapler closed creating the hysterotomy (fig. 2f). After creation of the hysterotomy, one or two figure-of-8 sutures were necessary for hemostasis at the wound apex.

Timing of initial entry with both trocars started with the placement of the introducer over the guidewire and ended with the closing of the stapler and creation of the hysterotomy. The primary surgeon estimated blood loss during initial entry. All the participating surgeons judged the convenience of use of each trocar. The times required for initial uterine entry were compared to an unpaired t test. Statistical significance was set at $p < 0.05$.

Results

In total, seven open fetal repairs of myelomeningocele have been performed at the University Hospital of São Paulo since August 2003. The first uterine entry was successfully achieved by the means of the Tulipan–Bruner trocar as recommended in the original protocol from the Vanderbilt Medical Center. From then on, six patients were randomized to initial entry either with the Tulipan–Bruner trocar or the newly designed Almodin–Moron trocar.

The time required for initial entry with the Tulipan–Bruner trocar was 35 ± 10 s (mean \pm SD), while it was 30 ± 10 s with the Almodin–Moron trocar ($p > 0.05$). No statistically significant difference in use between either of the trocars was found. Blood loss for all six cases was less than 50 ml, without any obvious difference between the instruments.

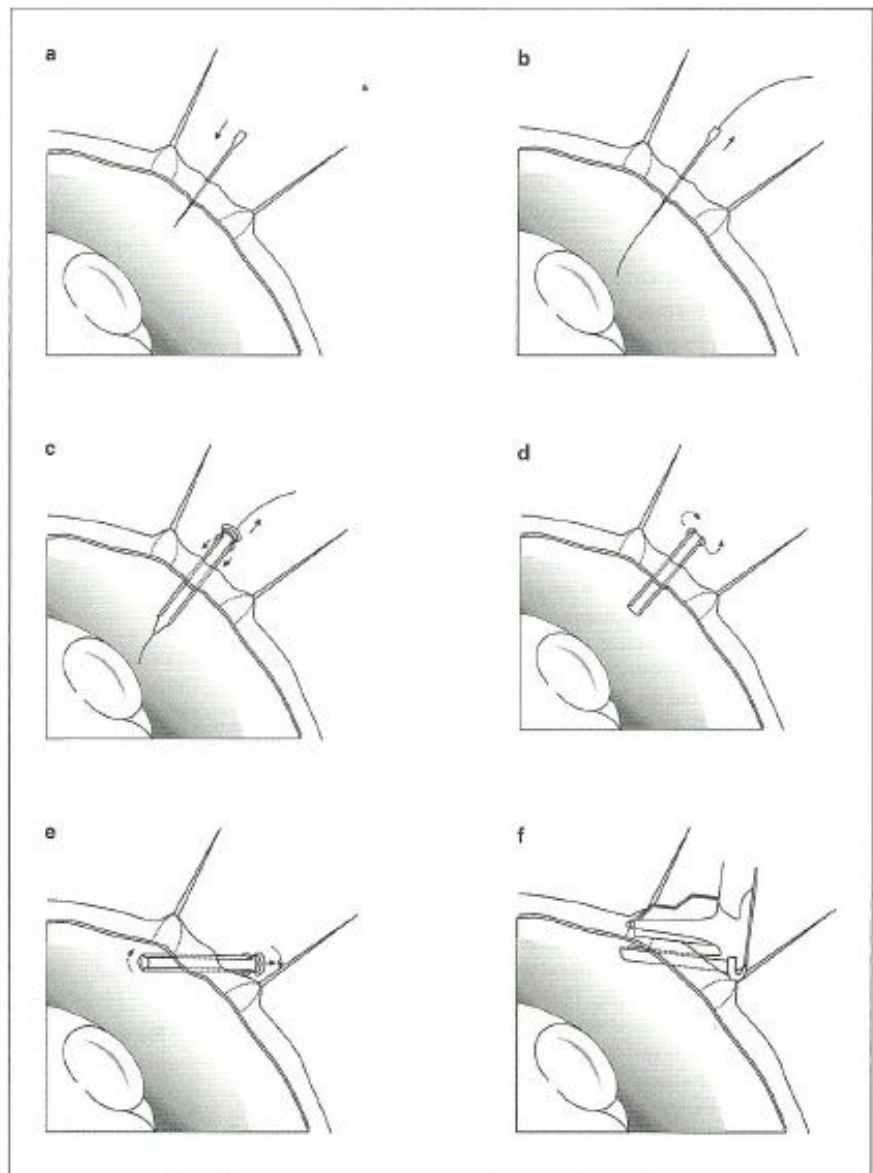


Fig. 2. The Almodin-Moron trocar is placed by a modified Seldinger technique (a-c). Metal sleeve helps direct the flow of amniotic (d). Clearing, introducer used to clear and to position sleeve close to uterine wall (e). Insertion of uterine autostapler (f).

Discussion

The ideal technique for uterine entry for open surgery would be quick, simple, atraumatic and bloodless. In relation to earlier techniques, the Tulipan-Bruner trocar has already been shown to be faster and less traumatic than the use of electrocautery for uterine entry, and the Seldinger technique applied is widely used in a series of surgical procedures [4].

As predicted by Bruner and Tulipan, [4] open fetal surgery is a recent development in pre-natal care that will offer the opportunity for intrauterine treatment of fetal disease. The Almodin-Moron trocar is a natural development in technology as the number of successful cases increases. We believe that the Almodin-Moron trocar is an instrument that not only performs at the same level of the original trocar without compromising the results, but also seems to have brought some advantages to the procedure especially in terms of handling and safety.

When the entry introducer is removed and the amniotic fluid flows out, there is the hypothetical risk that some part of the fetus (especially the umbilical cord) may be sucked into the sleeve outside the doctor's vision, and could later be injured by the introduction of the footplate of the stapling device. The use of the new atraumatic clearing introducer guarantees that the sleeve is free from any fetal parts. It can also be used to help position the sleeve close to the uterine wall in the right position for hysterotomy, rather than using the stapler itself to do it.

The stainless steel sleeve also seems to have some advantages over the original plastic sheath. Being made of metal, it permits easier handling during the drainage of the amniotic fluid than the thin plastic sheath. It is also 3 cm longer, and therefore, once the sleeve is cleared, the risk that the stapler goes beyond its end causing any kind of injuries to the fetus is practically non-existent. Because of these small modifications, the medical team involved

in the procedures subjectively considered the new Almodin-Moron trocar as convenient as the original Tulipan-Bruner trocar.

In conclusion, despite the small number of patients in the study, the new Almodin-Moron trocar seems to be a good option for uterine entry during creation of a hysterotomy. This study shows that it is as quick and causes as little trauma as the already established Tulipan-Bruner trocar. Encouraging as this work seems to be, clinical feasibility of the new trocar will demand further investigation.

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