Can A Novel Uterine Cannula (Atiomo-Dyeseal™) Minimise A False Diagnosis Of Proximal Tubal Obstruction At Laparoscopy And Dye Test For Infertility?


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Background  
The management of all infertile women requires an assessment of whether the fallopian tubes are open often by laparoscopy and dye test. The current cannulae either do not provide a tight cervical seal resulting in leakage of dye and poor intrauterine pressures with an increased potential for a false positive diagnosis of proximal tubal obstruction, or where they have a good cervical seal, do not have a distal component allowing uterine manipulation. The potential annual costs to the NHS of a false positive diagnosis of proximal tubal obstruction during laparoscopy and dye test range from at least £258000 to £3,586,000. A novel uterine manipulator (Atiomo-DyeSeal™) which provides a good cervical seal as well as a variable length distal component for uterine manipulation has been invented in Nottingham and been undergoing development.

The product is now CE marked, validated and in clinical use.

The aim of this study was to look at tubal patency rates with the Atiomo-DyeSeal™ uterine manipulator in current clinical use. Initial data from an ongoing study are presented.

Methods  
Tubal patency rates were audited in 22 fallopian tubes from 11 women undergoing a laparoscopy and dye test where the Atiomo-DyeSeal™ uterine manipulator was used. Tubal patency rates in 12 fallopian tubes from 6 women who had their laparoscopies and dye tests performed with the uterine manipulators in routine clinical use (Spackman’s and/or Leech Wilkinson) before the Atiomo-DyeSeal™ manipulator was introduced acted as controls.

Surgeons performing a laparoscopy and dye test at QMC Nottingham where the Atiomo-DyeSeal™ uterine manipulator was used were asked to fill out a standard proforma following the procedure. Apart from the diagnosis or not of tubal patency as assessed by the surgeon, other variables measured included the amount of dye used, approximate amount of dye backflow noted from the cervix, number of devices used to establish a diagnosis (i.e. was there a need to use a Spackman or a Leech Wilkinson’s) and complications. The assessments were carried out by 2 consultants and 4 specialist registrars.

The medical records of 6 women who had undergone a laparoscopy and dye test in the preceding one month before the introduction of the Atiomo-DyeSeal™ uterine manipulator into routine clinical use at QMC Nottingham were reviewed for the tubal patency and complication rates and used as the control group.

Results  
95.4% (21/22) of the fallopian tubes in women who had their laparoscopy and dye test performed with the Atiomo-DyeSeal™ uterine manipulator were patent compared with 83%in the control group (10/12), p >0.05.

The median amount of methylene blue dye required to assess the fallopian tubes at laparoscopy and dye test with the Atiomo-DyeSeal™ uterine manipulator was 7mls (range 3mls – 60mls). In seven of the women who had their laparoscopy and dye test performed with the Atiomo-DyeSeal™ uterine manipulator, no
dye leak (backflow) was noted from the cervix and in four women some leakage was noted. However, of these four women, three women leaked less than 5 ml and one woman leaked more than 10 ml of dye. This compared with a 100% dye leakage rate using the Spackman cannula noted in a previous study.

All the procedures were completed with only one device in women who had their laparoscopy and dye test performed with the Atiomo-DyeSealTM uterine manipulator; however one woman in the control group also had to have a Foley’s catheter used in an attempt to improve the cervical seal. There were no adverse events reported in all 17 women.

Conclusion
Our results demonstrate that the Atiomo-DyeSealTM uterine manipulator could potentially reduce the incidence of a false positive diagnosis of proximal tubal obstruction. 95.4% (21/22) of the fallopian tubes in women who had their laparoscopy and dye test performed with the Atiomo-DyeSealTM uterine manipulator were patent compared with 83% in the control group (10/12), p >0.05. The significance of these findings will however need to be validated in a larger study. The design of the Atiomo-DyeSealTM uterine manipulator has features which may benefit patients by reducing the incidence of a false diagnosis of proximal tubal blockage because of the better cervical seal generated1. In this study 7 of the 11 women studied did not leak any dye from the cervix and 10 of the 11 women leaked 0-5 ml of dye.

The incidence of a false positive diagnosis of proximal tubal obstruction during dye hydrotubation procedures ranges from 7.41% during laparoscopy and dye test to 40% during dye hydrotubation procedures where intrauterine pressures are shown to be low.

This false positive diagnosis of proximal tubal obstruction has been shown to be reduced by 28% to 72% following the generation of higher intrauterine pressure with a better cervical seal. In 2005/2006 in the NHS, there were 6228 laparoscopies and dye tests performed for infertility. Based on these data 461 (7.41%) to 2491 (40%) could have had a false positive diagnosis of proximal tubal obstruction due to the failure to generate high intrauterine pressures from a good cervical seal. The generation of a better cervical seal could have potentially reduced this figures by 129 (28%) to 331 (72%) in the best case scenario (i.e. 7.41% false positive diagnosis rate); or 697 (28%) to 1793 (72%) in the worst case scenario (40% false positive diagnosis rate). Women with a diagnosis of proximal tubal obstruction are managed by either in-vitro fertilisation or tubal surgery.

Each procedure (IVF or tubal surgery) costs approximately £2000 in the UK, and several cycles of IVF may be required. The potential annual cost savings to the NHS from the generation of a better cervical seal and the reduction of a false positive diagnosis of proximal tubal obstruction during laparoscopy and dye test therefore range from at least £258,000 to £3,586,000. The Atiomo-DyeSealTM uterine manipulator by stopping dye leakage generates better intrauterine pressures with a potential for reducing the clinical and economic costs of a false positive diagnosis of proximal tubal obstruction.

References

Conflict of Interest: William Atiomo is a named inventor on the pending patent application for the Atiomo-DyeSealTM Uterine Manipulator. The patent is also assigned to the University of Nottingham. Ivor Rowe works for the manufacturing company to which the device has been licensed.