Dear Editor,

Uterine manipulators usually used for the laparoscopy and dye test, such as the Spackman, Cohen or Jarcho cannulas are associated with dye leakage because of a poor cervical seal. Where a good seal is generated as with the Leech Wilkinson cannula, uterine manipulation is post Dye leakage from the cervix could lead to the generation of insufficient intrauterine pressures and an increased diagnosis of proximal tubal blockage [1]. To overcome these challenges, a novel (Atiomo-DyeSea™) uterine manipulator has been designed in Nottingham (Fig. 1). The Atiomo-DyeSea!™ provides a good cervical seal and uterine manipulation without the need for an intrauterine balloon. The Atiomo-DyeSea™ is disposable because of recent concerns about the risks of transmitting health care associated infections [2] as hollow devices, which are used to inject fluid into the uterine cavity, create a problem because the canal is difficult to sterilise appropriately. We would like to report our initial experience with the Atiomo-DyeSea!™.

Following institutional review board approval, 13 women undergoing a laparoscopy and dye test had the Atiomo-DyeSea™ used and 11 women acted as controls. Five gynaecologists carried out the procedures and feedback was also sought from three assisting doctors. For the Atiomo-DyeSea!™, three very similar design prototypes were evaluated to assess performance. The Mark one was used in two women and modified after some design issues were raised (specifically the need to widen the base of the cone and amend the locking clip). Both women had bilaterally patent tubes. The Marks two and three were then produced and used for the remaining 11 women. Twelve of the thirteen women in the Atiomo-DyeSea™ group had the Atiomo-DyeSea™ used and one woman had a Spackman’s cannula used in addition, to verify the diagnosis. Ten of the eleven women in the control group had a Spackman’s cannula alone used in their procedure and one woman had a Leech Wilkinson’s cannula alone used. There was no significant difference in parity between both groups.

The median amount of dye used was lower with the Atiomo-DyeSea™ (20 mis (4.5-100) versus 30 mis (6-60)) and cervical dye leakage was significantly less common (6 of 13 (46%) versus 11 of 11 (100%), p < 0.05). With the Mark one device dye leakage was noted in one woman. With the Mark two (in current clinical use) dye leakage was noted in only two (25%) of the eight women who had it used. With the Mark three all three women who had it used leaked some dye, so this device is not currently in clinical use. There was no difference in the proportion of women with bilateral tubal patency. There were no adverse events reported. The Atiomo-DyeSea!™ Uterine Manipulator was thought to meet a clinical need by all gynaecologists (100%) and the two advantages noted over the existing products on the market were that the Atiomo-DyeSea™ resulted in a better cervical seal and better uterine manipulation.

A post hoc sample size calculation showed that 12 women would have been sufficient in each arm of our study to detect the differences in dye leakage rates found with a power of 90% and a type 1 error of 0.05. We are not aware of any other report on leakage rates with the Spackman cannula. As chromotubation techniques which are associated with a better cervical seal have been shown to generate higher intrauterine pressures [3] and higher intrauterine pressures at dye hydrotubation are associated with the demonstration of bilateral tubal patency in women who were initially thought to have blocked fallopian tubes [4], the Atiomo-DyeSea™ Uterine Manipulator may reduce the incidence of a false diagnosis of proximal tubal blockage.

Conflict of interest

1. William Atiomo: William Atiomo is a named inventor on the pending patent application for the Atiomo-DyeSea™ Uterine Manipulator. The patent is also assigned to the University of Nottingham.
2. Shilpa Deb: None.
3. Susnata China: None.
4. James Hopkisson: None.
5. Martin Powell: None.
6. Ivor Rowe: Ivor Rowe works for the manufacturing company to which the device has been licensed.

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Fig. 1. Longitudinal view of Atiomo-DyeSeal™ Manipulator from the rear perspective. The cannula has an inner hollow cannula within an outer cannula, which has a proximal threaded acorn which is used to seal the cervical canal. The outer cannula can move axially up and down the length of the inner cannula making it possible to adjust the intrauterine portion to take into account varying uterine sizes. A locking clip is also provided distal to the outer cannula to lock it in place once inserted into the uterine cavity to prevent accidental distal slippage of the inner cannula into the uterus during dye hydrotubation and a movable holding clip to attach a vasculum forceps is also provided on the outer cannula.

References


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