Title Assessment of anti-Müllerian hormone serum assay

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Aim

The primary aim of this discussion paper is to assess the usefulness of the anti-Müllerian hormone assay procedure (AMH) with a view to its inclusion in the NABM (Nomenclature of Procedures in Laboratory Medicine).

Conclusions and results

Analysis of the available data leads to the following conclusions:

- The pre-analytical and analytical performances of automated tests (third-generation assay kits) are superior to that of manual tests (first and second generation). Manual tests should be replaced with automated tests;
- In the absence of an international standard, for all the indications listed below the threshold value is dependent on the assay technique used;
- Clinical situations in which AMH testing is appropriate:
  - predicting poor and excessive ovarian response in the context of ovarian stimulation in addition to antral follicle count (AFC) and as a substitute for inhibin B;
  - managing female infertility in women who have undergone or are due to undergo anti-cancer treatment in addition to AFC when the latter is a viable option;
  - treating women with pelvic gynaecological conditions (endometriosis, ovarian cysts) as a substitute to AFC and inhibin B;
  - diagnosis and monitoring of granulosa cell tumours in addition to inhibin B;
  - differential diagnosis of sex development disorders;
- No threshold value of AMH has been validated for the characterisation of morphological polycystic ovaries within the context of the diagnosis of polycystic ovary syndrome in patients unable to have AFC by endovaginal ultrasound (virgins) or when AFC performance is diminished (namely in obese patients), when one of the two other Rotterdam criteria (oligo-anovulation and hyperandrogenism) is not present;
- Clinical situations in which AMH assay is not indicated:
  - predicting implantation, pregnancy or birth in a setting of medically-assisted reproduction;
  - predicting the age of menopause or premature ovarian insufficiency;
  - prognosing spontaneous fertility in healthy women;
- Clinical situations in which the data does not allow any conclusions to be drawn about the relevance of the assay:
  - diagnosis and monitoring precocious puberty;
- In light of the poor prognostic performance of inhibin B in the various approved indications, it would be appropriate to consider replacing it with AMH assay, except in its use as a granulosa cell tumour marker.

The main prospects that emerge from this assessment have to do with improving the design of studies that include AMH in order to better adapt ovarian stimulation strategies and the development of research into the clinical utility of AMH assays in cases of male hypofertility.

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