

# LETTER TO THE EDITOR: Septate Uterus and reproductive outcomes: let's get serious about this

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LETTER TO THE EDITOR

## Septate uterus and reproductive outcomes: let's get serious about this

Sir,

We write in regard to the recent paper in *Human Reproduction*, Rikken *et al.* (2020) entitled 'Septum resection in women with a septate uterus: a cohort study'. The authors present a multicenter study aiming to compare the reproductive outcomes of hysteroscopic metroplasty versus expectant management in a cohort of infertile women desiring to conceive. We congratulate the investigators on the effort, since we recognize the need to search for evidence on this highly debated topic. In this regard, we agree with the authors that randomized controlled trials (RCTs) are needed to clearly understand the benefits of hysteroscopic metroplasty in the infertile patient with septate uterus. However, the conclusions reported in this study are not supported by the provided evidence and might lead to misunderstandings, given the numerous methodological limitations and biases present in the article.

The first bias is the large number of centers from which the data were obtained (18 centers in the Netherlands, 2 centers in USA and 1 in the UK), and the long recruiting time frame included in the study (from January 2000 until August 2018) which results in an average of

that pregnancy as obstetrical history and all subsequent pregnancies as follow-up'. Nevertheless, based on the results and methodological description, it is unclear whether the ongoing pregnancies at the time of septum diagnosis were counted as live birth. Regardless of this element, it is further questionable to include women already pregnant at the time of uterine septum diagnosis.

The third element of concern is the immortal time bias (Porta, 2016, p. 142), which affects the treatment group. Indeed, it is questionable and represents an error that the time to event analysis started from the moment of diagnosis. Women who underwent hysteroscopic metroplasty were forced to delay conception until the surgical procedure was performed, introducing a delay in the potential achievement of the live birth. This, without considering the possible waiting time required after the surgical treatment, since this information is not provided in the manuscript. Therefore, these patients were not exposed to their full capacity to conceive until they reached a certain length of follow-up time, raising concerns of an artificially low event rate and a right shift of the 'treatment' curve. On that basis, all the analyses should have been conducted excluding women already pregnant at the time of the diagnosis and counting the time to event from the moment in which the women started to attempt to conceive.

In addition, another important limitation of this study is that no information is provided about other possible causes of subfertility in the couples, such as male factor infertility. In this regard, no information is

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Letter to the editor in regards to the paper 'Septum resection in women with a septate uterus: a cohort study' published in *Human Reproduction* (Impact Factor 5.733), the official Journal of the European Society of Human Reproduction and Embryology (ESHRE) and published by Oxford University Press:

The letter is signed by:

Luis Alonso Pacheco, Bari? Ata, Stefano Bettocchi, Rudi Campo, Jose Carugno, Miguel Angel Checa, Carlo de Angelis, Attilio Di Spiezo Sardo, Jacques Donnez, Martin Farrugia, Jaime Ferro, Mario Franchini, Simone Garzon, Luca Gianaroli, Marco Gergolet, Giampietro Gubbini, Stephan Gordts, Grigoris Grimbizis, Sergio Haimovich, Antonio Simone Laganà, T C Li, Luca Mencaglia, Laura Rienzi, Sotirios Saravelos, Sergio Reis Soares, Vasilis Tanos, Alicia Ubeda, Filippo M Ubaldi, Bruno Van Herendael, Attila Vereczkey, Amerigo Vitagliano, Salvatore Giovanni Vitale, Fulvio Zullo.

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