Self-operated endovaginal telemonitoring (SOET): a step towards more patient-centred ART?

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The problem to be debated

Although initial attempts at obtaining a pregnancy by in vitro fertilization and embryo transfer (IVF-embryo transfer) were conducted in a natural cycle (Edwards et al., 1980), it was soon recognized that ovarian stimulation using gonadotrophins was needed in order to obtain more oocytes and increase the chance for success by morphology-based embryo selection. The need to monitor ovarian stimulation has, for some time, been based on serial sonographic assessments of follicular growth (Kemeter and Feichtinger, 1989) and to a lesser degree on serial measurements of serum estradiol. These became less important since sonography, after shifting from the abdominal to the vaginal route, became the most important monitoring tool, as well as the preferred route for oocyte aspiration. The relevance of estradiol measurements is limited to cases of threatening ovarian hyperstimulation syndrome (OHSS), whereas serial sonography, as the sole method of monitoring follicular growth, has become routine and cannot be dispensed with, both for optimal timing of hCG administration and for early detection of OHSS.

Patient-friendly artificial reproductive technology (ART) gently creeps into our clinics (Pennings and Ombelet, 2007) and includes self-administration of gonadotrophins, newer gonadotrophin formulations, milder stimulation protocols (Baart et al., 2007), reduction of multiple pregnancies by judicious single embryo transfer (Gerris et al., 2002), a decrease of the risk for OHSS, more efficacious embryo freezing programmes (Tiitinen et al., 2004) and less treatment-induced stress. The embryo utilization rate has improved. Fewer multiples are born for an equal or even enhanced pregnancy chance per attempt. Milder protocols result both in reduced side-effects and substantial savings for patients or third-party funders. Natural or minimally modified natural cycles, as well as in vitro maturation, also help to avoid or minimize the gonadotrophin use (Pelinck et al., 2006). Further simplifications in the pipeline comprise the use of long-acting injectable gonadotrophin preparations allowing reductions in the number of injections and the total dose of gonadotrophins, and oral gonadotrophins.

Notwithstanding these helpful developments, one major inconvenience still persists, i.e. the need for women to visit the IVF clinic or their gynaecologist to perform serial vaginal sonographies. No hard data exist regarding the average number of pre-oocyte-retrieval sonographic visits which may vary substantially between centres. In our centre, the last 100 in-house IVF cycles needed 440 follicular phase sonographies, including the starting sonogram. The total annual number of IVF/ICSI attempts amounts to approximately 1 million and is probably still rising. It is not exaggerated to add another 1 million of non-IVF/ICSI stimulations. This implies between

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8 and 10 million annual sonograms for pre-ovulatory ART-monitoring only or, for ~300 working days per year, a trek to the IVF clinic for 90 000 women per day! But SOET has more to it than just reducing the number of sonographies performed at a centre. It can significantly increase access to treatment itself. Huge distances in large countries, whether they belong to the first, the second or the third world, where sonography is not available within a reasonable distance from homes, decrease access to treatment for many couples who could benefit from it. This is the case in large developed societies, e.g. the USA, Australia, Canada and other giant countries, but also in many countries in the developing world where assisted reproductive services are scarce, although on the rise. The two major impediments to wide access to ART overtly identified are cost of treatment and legal limitations. Recent attention has been given to so-called ‘IVF in low-resource settings’ to be implemented in third-world countries with poor access to treatment because of financial constraints. It is a noble intention of making subfertility a global issue because of its severe social consequences in all human societies. High costs and legal obstacles indeed may hamper treatment. But we must recognize that limited access to ART treatment exists almost everywhere. This follows from the wide variation in the number of ART cycles per number of inhabitants between different countries (e.g. Nyboe Andersen et al., 2008), ranging from >2000 cycles/million inhabitants to just a few hundred cycles/million inhabitants as in the USA or a mere 20/million inhabitants in India. High access rates are usually observed in small countries, e.g. Denmark, Israel and Belgium. Low access is observed in larger countries, where sheer distance and/or the time needed to cover it, severely limit treatment utilization, even in high-resource settings. Whether it be the Australian out-back, the American mid-west, the Russian steppes, the deep interior of rural India or China, or the more remote areas of many other countries, distance and/or the time needed to reach expert sonography plays a preponderant role in making ART a feasible option for many patients who need it.

An idea that may help solve the problem

To solve this problem, we suggest the idea to have patients have their sonographies perform themselves (Fig. 1), after instruction by a midwife, a nurse-practitioner or an experienced sonography technician, using a small, re-usable, safe, cheap and easy to use customized device, allowing registration of real-time images under direct visual inspection of the patient or her partner. Images can be sent with proper identification over the internet to the centre where specialized personnel and technology receives, stores, analyses and interprets the images followed by swift appropriate action, i.e. dosage adaptation or next-step decisions. These responses could be semi-automated by using specific software. They should comprise proper instructions regarding the dose of gonadotrophins to be self-injected during the following day(s), the timing for a subsequent sonogram, the precise timing of hCG injection and of oocyte retrieval. If extended to intrauterine insemination or freeze/thaw cycles after IVF, even in a natural cycle or after oral ovulation induction, planning of insemination or embryo replacement can be communicated. If needed, these self-operated endovaginal sonographies (SOETs) could be performed with a backup of same-day ‘live’ or next-day ‘real-time’ sonography in the centre. The idea could work for IVF/ICSI cycles but it could be extended to non-IVF ovarian stimulation protocols using oral or i.m. drugs.

Several questions and considerations need to be addressed, amongst others (re)organizational aspects, protection of privacy (who has access to the data?), legal (who is responsible for errors...
resulting in complications?) and financial aspects (who will pay the interpretation, storage, communication, etc. given the loss of direct income linked to individual sonographic procedures?). We will address these secondary aspects after considering the present experience in IVF.

It is not the idea to replace all vaginal sonography in the context of IVF, let alone all gynaecological sonography, by SOET. ‘Real-time’ sonography will remain a very important tool in IVF. During a transitional phase of acceptance of SOET, and even if accepted, SOET will not replace sonography in complicated cases, when follicular growth is abnormally slow or quick, when abnormal images (cysts, hydrosalpinges, unexpected tumours, endometriosis, etc.) are observed, or on simple request from anxious patients. It is suggested in the first place to alleviate an abnormal amount of time-consuming, routine work and to allow patients living far from the centre to make less demanding sacrifices.

**Potential advantages of SOET**

A comparison between the disadvantages of the present way of monitoring ovarian stimulation for ART and the advantages of self-operated home sonography is pictured in Figs 2 and 3. The possibility for patients to perform vaginal sonographies themselves at home includes the following theoretical advantages. Patients need not to come as often to the centre to have sonographies performed. They will save time and money spent on petrol, car usage, train or bus. They and their partners will avoid loss of income during working hours. Weekends and their important social and household functions will not be interrupted by half- or full-day trips to the centre. Centres performing IVF will be less crowded by patients only needing a sonogram, mainly during morning hours. Much of this work is at present poorly standardized, relies on authority-based algorithms and decision models, and could for that reason also benefit from a potentially quality-enhancing development, such as SOET could be. Indeed, measurements will be more standardized and reproducible and can be performed at ease, allowing decreased inter-observer variation. At present, patients expect immediate results and appropriate decisions when they come for on-site sonographies, which does not increase quality. Alternatively, they must call the centre later during the day when oocyte-retrieval schedules have been fixed for the next day or two. Communication with the patient will be smoother, more complete and contain all information needed in print. Images sent can be accompanied by questions that can be answered properly and not in a hurry by a stressed doctor, midwife or nurse. More time will thus be available for truly necessary interactions between doctors/nurses and patients who still need to, or prefer to, come physically to the staff at the centre, reducing excessively long waiting lists for consultations. Treatments will become possible in patients who live far from the centre, allowing them to travel just before egg retrieval from, theoretically, anywhere in the world. It is a development that fits in a flat world where telemedicine has already found a firm place in other fields of medicine e.g. radiology, cardiology, antenatal home cardiotocography, etc. Structured e-mail communication regarding treatment instructions has already been reported (Mimoni et al., 2009) and is undoubtedly in use in many centres. When combined with telesonography, it allows patients to be treated in the centre of their choice and not necessarily in the centre that happens to be closest to their home. It increases patient autonomy. It is conceivable that SOET could have a place in ART, not only in developed countries, but in the developing world as well, where women in rural areas could have sonograms performed by a local sonographist, using a single instrument for several patients, the data being sent with

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**Figure 2** Disadvantages of traditional monitoring and potential advantages of SOET.
proper identification of patients to the nearest centre where egg retrieval and laboratory phase will be conducted.

There may be other, indirect but nevertheless equally important, advantages of SOET. One is the ecological effect. In our quickly changing climate, frequent trafficking adds imperceptibly but substantially to using up limited energy resources and creating exhaust. The other is the sheer feeling of empowerment women may feel when participating actively in their treatment. The often exaggerated personalized contact with the treating physician, already diluted by the team-aspect of ART, may be better served by using webcam-mediated personal contacts with the coordinating physician, once he or she is duly known and trusted by the patient. Sonograms can also be made by the partner who is in 50% of cases at the origin of the subfertility and in many cases will be more than happy to be able to participate in an active way in a treatment that involves his partner more than it does himself. First thing is to try and find out whether patients would welcome the possibility to perform vaginal sonograms themselves. Second is to assess whether those who are positive towards the idea are actually able to produce good quality video recordings of their internal genital organs. The third issue is to find a technically satisfying and affordable solution that in the first place fits the needs of those who require ART, wherever they live.

**Preliminary clinical experience with SOET**

Although this is no more than an opinion article, at present, SOET is already something more than just an idea. We have addressed several questions in preliminary clinical research after obtaining formal approval from our local Ethical Committee.

First, we questioned 25 couples regarding their attitude towards SOET. Patients’ and their partners’ positive attitude towards a self-operated vaginal sonographic technology was highly enthusiastic. Perceived advantages were avoidance of frequent hospital visits, time loss, petrol cost, organizational stress and ease of treatment. There were no objections to introducing a device into the vagina. Most partners seemed to be willing to ‘help’ in this regard, potentially replacing a strenuous patient-sonographist encounter by an intimate couple contact. All but one couple found no problem with computer use.

Second, we sought proof of concept using an experimental set-up within the centre. Twenty patients completed their attempt and all performed all sonographies themselves as requested. Images were sent over the hospital intranet as a proxy for the worldwide internet, stored at the receiving end and could be endlessly replayed for quiet measurement and analysis. All consented on a very positive experience, as did the midwives involved in the study. We therefore conclude that patients’ acceptance of self-echography and performance were high. The readiness and reliability of women to visualize their own internal genital organs, recognize the structures, in particular the thickening endometrium and the growing follicles, elicited great interest and cooperation and was highly successful. Relevant images were easily recognized as soon as early follicular development became visible. The need for a didactic reference document exhibiting the most relevant images (bladder, endometrium, follicles) was noted and opens a line for midwife research to standardize and optimize such a teaching tool as an adjunct to ‘sono-anatomy’ of the female pelvis. The issue of training requirements will be actively addressed in the next step in the development of SOET. Standard illustrations

![Figure 3 Disadvantages of traditional monitoring and potential advantages of SOET.](image-url)
of typical images during treatment will be offered to patients and at least one personalized teaching session by a specialized midwife will be organized for each new patient.

Several other important clinical and ethical aspects of the implementation of SOET must be addressed proactively in a structured way, amongst others preservation of confidentiality of patient data and the potential impact of suboptimal compliance of patients with the technology. Definitely, any new approach should be compared with existing technology, both from the point of hard results, patient satisfaction, potential hazards and cost. A direct comparison between traditional monitoring and SOET, both with respect to pregnancies obtained and potential failure, must be conducted in methodologically valid clinical studies where both approaches are used in parallel.

Technological aspects

The further development of a specific device for home sonography was deemed to be dependent on a positive experience in these initial steps. It is important to realize that SOET is not a simple and straight application of existing technology in a particular clinical setting. Specific research is needed with respect to several technological aspects. This research has to be focused on the low-end instead of the high-end spectrum of sonographic instruments, in order to make the device as cheap as possible.

The low-end apparatus to be developed for this very specific application need not necessarily yield the same high-quality images as existing sonographic instruments. Essentially, it must yield images that will induce the responsible clinician to make the same clinical decisions as those made using the high-end devices. This requires adapting and customizing existing technology. The crux is to produce an instrument at a substantially lower cost than existing ‘portable’ sonographic machinery, resulting in the same clinical efficacy, while reducing the disadvantages and side-effects of static in situ sonography and not decreasing the safety of the treatment. The instrument must be light, strong, easy to transport and use for the woman and her partner. This implies simplification and customization of the lay-out, usage, ergonomy, recording and image-sending instructions of the instrument to be used by individuals not necessarily familiar with electronic equipment. Ideally, the probe should be made ‘intelligent’, i.e. directed towards recognizing ovarian tissue, follicular (=cystic) sonographic patterns and ‘movable’, i.e. make angular movements on command after introduction into the vagina, thereby limiting hand and wrist movements users would have to make themselves in order to visualize the ovaries; however, production cost considerations should be preponderant over gadget value or design.

It is not inconceivable to implement software for automated measurements of follicular diameter which has been documented at

The SOET approach needs to be integrated into the future of tele-medicine that is about to emerge worldwide and find applications in our flat globe wherever IVF is requested.

Health-economic and ecological considerations

A full health-economic study of the alleged advantages of SOET has to be conducted, addressing all direct and indirect issues, including ecological, economical and psychological aspects.

Finally, viable business models adapted to specific societal circumstances have to be developed. The players and potential beneficiaries of this new approach are depicted in Fig. 4.

In parallel with the technical and clinical development of SOET, we will need to initiate a long-term reflection on the payment for the sonographies. This will in a large part be influenced by developments on a political level. Reasons to choose for SOET will be quite different between countries. Where patients pay, the instrument should be marketed in such a way as to reduce the (high) total cost for the patient. Where public insurance pays, as in Belgium and other European countries with a social security system, the challenge will be to create savings for the government without increasing the (already limited) cost for the patient in order to reach an equilibrium that makes for a classical win(patient)-win(centre)-win(government) situation, as has been the case with the SET (single embryo transfer) project. In Belgium, at present, the laboratory costs of IVF/ICSI are paid for by the government with a fixed amount, whereas medical procedures are subject to third-party payment using negotiated fixed ‘prices’. Even gonadotrophins used for IVF/ICSI are now funded by fixed amount payments per attempt leading to an oocyte recovery. It seems logical to expect that before long the monitoring of the follicular phase and, to a lesser extent, the luteal phase, will also be paid for with agreed fixed amounts. Should that occur, one fixed amount will be paid for all the aspects, i.e. for the whole of an IVF/ICSI cycle. From that moment onwards, there is no reason at all for centres to perform (too) many sonographies. Easy routines could be done at a distance, by the patient herself, at home, eventually with the help of an otherwise passively involved partner.

A question that needs answering is: SOET for whom? In a first phase, only motivated ART patients are likely to be interested, especially those who have had at least one attempt already. Full instruction by a midwife to get acquainted with the sono-anatomy of the female pelvis is mandatory. Backup using traditional sonography must remain available. Only if wanted by the patient, should the method be considered. Later extensions may be possible to other infertility treatments or to early pregnancy could be possible but initially it should be used exclusively for regular ART stimulations.

Is there a ‘market’ for SOET? In Belgium, the annual number of IVF/ICSI attempts has stabilized around ~15 000/year. An educated guess would be that ~50% could be candidates for SOET. Worldwide, there are ~1 000 000 attempts/year of which half take place in Europe. A further increase of this number is likely but hampered by poor access for which SOET could be a solution. This is especially the case in all large countries of which a number are at the same time third-world countries, where there is a quickly emerging market for reproductive technologies.
An invitation to join the debate: who is afraid of SOET?

We recorded almost unanimous enthusiasm in all patients and their partners for the development of SOET as a tool to ease the burden and stress of monitoring follicular growth due in part to the obstructed traffic in our megalopolis society.

Our initial experience in women who along their regular treatment, performed all their sonographies in duplo themselves, was positive in the sense that it produced usable images and gave a feeling of empowerment to the women.

SOET appears to be a welcome idea and the concept is proven. The next phase will consist in designing and implementing a specific portable instrument via a truly home-to-centre internet connection and further document the clinical validity of the concept.

The prerequisites are: ease and safety of introduction into the vagina, ease of handling in recording and in sending the recordings, connection modalities to most commercially available home computers, possibility of repeated usage within the centre, low cost to fit in any realistic health-economic perspective (from the point of view of the patient, the manufacturer, the centre and the health insurers).

These a priori considerations, supported by initial clinical experience, can be used as a starting point to explore in a systematic way the potential value of a home-based sonographic approach. A lively debate with pros and cons could follow.

Ten years ago, the fruitful debate on single embryo transfer was opened with one simple innocuous question: who is afraid of SET? (Coetsier and Dhont, 1998). Since then, SET has become an important issue in ART and the standard in many countries.

The question now is: who is afraid of SOET?

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References


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