Current Developments from Silicon Valley – How Artificial Intelligence is Changing Gynecology and Obstetrics

Aktuelles aus dem Silicon Valley – wie künstliche Intelligenz die Frauenheilkunde verändert

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ABSTRACT

Artificial intelligence (AI) has become an omnipresent topic in the media. Lively discussions are being held on how AI could revolutionize the global healthcare landscape. The development of innovative AI models, including in the medical sector, is increasingly dominated by large high-tech companies. As a global technology epicenter, Silicon Valley hosts many of these technological giants which are muscling their way into healthcare provision with their advanced technologies. The annual conference of the American College of Obstetrics and Gynecology (ACOG) was held in San Francisco from 17-19 May 2024. ACOG celebrated its AI premier, hosting two sessions on current AI topics in gynecology at their annual conference. This paper provides an overview of the topics discussed and permits an insight into the thinking in Silicon Valley, showing how technology companies grow and fail there and examining how our American colleagues perceive increased integration of AI in gynecological and obstetric care. In addition to the classification of various, currently popular AI terms, the article also presents three areas where artificial intelligence is being used in gynecology and looks at the current developmental status in the context of existing obstacles to implementation and the current digitalization status of the German healthcare system.

ZUSAMMENFASSUNG

Künstliche Intelligenz (KI) hat sich zu einem allgegenwärtigen Thema in den Medien entwickelt. Lebhafte Diskussionen halten an, wie KI die globale Gesundheitslandschaft revolutionieren könnte. Die Entwicklung innovativer KI-Modelle wird zunehmend durch große Hightech-Konzerne dominiert, auch im medizinischen Bereich. Das Silicon Valley, als globales Technologieepizentrum, beherbergt viele dieser Tech-Giganten, die mit ihren fortschrittlichen Technologien in die Gesundheitsversorgung drängen. Vom 17. bis 19. Mai 2024 fand dort, in San Francisco, der Jahreskongress des American College of Obstetrics and Gynecology (ACOG) statt. Mit 2 Sessions feierte die ACOG eine KI-Premiere auf dem amerikanischen Fachgesellschaftskongress, in denen aktuelle Themen der KI in der Frauenheilkunde vorstellt werden. Dieser Beitrag bietet einen Überblick über die diskutierten Inhalte und ermöglicht dadurch einen Einblick in die Denkfabrik des Silicon Valley, zeigt auf, wie dort Technologieunternehmen wachsen und scheitern, und beleuchtet, wie unsere amerikanischen Kolleginnen und Kollegen die zunehmende Integration der KI in die gynäkologische und geburtshilfliche Versorgung wahrnehmen. Neben der Einordnung verschiedener aktuell kursierender KI-Begrifflichkeiten stellt der Artikel 3 Anwendungsbereiche von künstlicher Intelligenz in der Frauenheilkunde vor und betrachtet den aktuellen Entwicklungsstand im Kontext bestehender Implementationshürden sowie vor dem Hintergrund des Digitalisierungsstands des deutschen Gesundheitssystems.

Background

Silicon Valley: meeting place of the tech giants

Silicon Valley. located in the southern San Francisco Bay Area in California on the West Coast of the USA, is known around the world as the global center for high-tech and innovation. From the middle of the last century, the area has evolved into a hotspot for groundbreaking technological inventions, starting with the research into and development of silicon-based transistors, from which the Valley took its name [1]. Originally, what is now Silicon Valley was a predominantly agricultural region, known as the Valley of Heart's Delight due to its popular orchards. The decisive shift from agriculture to becoming an epicenter of technology began under the aegis of Frederick Terman, the dean of the School of Engineering of Stanford University. Terman encouraged the teaching staff and graduates of Stanford University to set up their own companies, and in 1951 he launched the Stanford Industrial Park, later renamed the Stanford Research Park, with part of the site leased by the university to emerging technology companies [1]. The companies include spin-offs from university departments such as Hewlett-Packard, Google, and Varian Medical Systems. In the 1980s and 1990s, research and industry in Silicon Valley began to diversify away from the manufacture of semiconductors towards the development of computers and the development of software- and internet-based companies [1]. Today, the region is home to world-leading technology companies pushing for the increased integration of artificial intelligence (AI) into everyday life, a development which is also beginning to affect the healthcare sector. But the scandal surrounding the start-up company Theranos, formerly sited in Stanford Research Park, shows just how close together the potential and the risks can lie when developing modern healthcare technologies. The company, which had a corporate value of 9 billion US dollars in 2015, collapsed rapidly in 2018 after investigations by journalists uncovered deceptive promises about revolutionary diagnostic technologies [2]. This is just one example which highlights the importance of structured and scientifically substantiated validation processes for emerging healthcare technologies.

ACOG Annual Clinical and Scientific Meeting 2024 in San Francisco

The annual conference of our American sister society (the American College of Obstetrics and Gynecology, ACOG), known as the ACOG Annual Clinical and Scientific Meeting 2024 (ACSM), was held in the immediate vicinity of Silicon Valley, in San Francisco, from 17–19 May 2024. For the first time, the ACSM included two sessions on the topic of artificial intelligence (AI). The sessions "Cutting-Edge AI Applications" and "Generative AI" presented and discussed recent artificial intelligence developments in gynecology and obstetrics, with representatives from leading technology companies from Silicon Valley sitting in on the presentations.

To make the contents of these talks available to the readers of "Geburtshilfe und Frauenheilkunde" this review provides an overview of current AI terms against the backdrop of the digitalization status of the German healthcare system, describes three areas presented at the ACSM 2024 where AI is already being used in gynecology, and looks at the current development status in the context of existing impediments to implementation.

Status of Digitalization in Germany and the Commission Digital Medicine of the German Society for Gynecology and Obstetrics (DGGG)

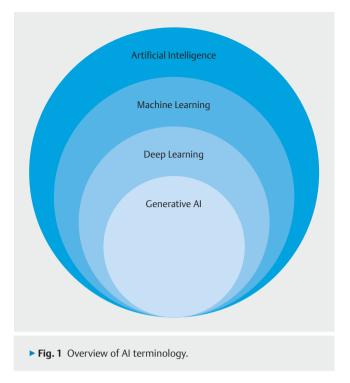
In recent decades, the German healthcare system has not excelled at promoting digitalization. But at the start of 2023, the Federal Ministry of Health in Germany issued its "Digitalization Strategy for the Healthcare and Nursing Sector" which provides a regulatory framework and aims to reduce the existing digitalization gap [3]. The very same year, two laws were also passed in Germany, the "Digital Act" (Digital-Gesetz, DigiG) and the "Health Data Use Act" (Gesundheitsdatennutzungsgesetz, GDNG), which provided a basis for the extensive digital reform plans of the Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) [4, 5]. With the establishment of the Commission Digital Medicine in February 2022, the DGGG has taken a further step towards digitalization with the aim of dealing more actively with the impact of the relevant regulations and the rapid implementation of modern healthcare technologies in both gynecology and obstetrics. Among other things, this also includes making current developments and discussions about AI, which is now an omnipresent topic in the media, more accessible to the members of its own specialist society.

Artificial Intelligence and its Promise to Health

The Artificial Intelligence (AI) Index Report 2024, published by the Human Centered AI Initiative of Stanford University, has collected, analyzed, and visualized data and issued almost 500 pages on data about AI in all areas of life [6]. The most important insights were summarized in a Top 10 list and a number of visionary conclusions were formulated. They include, for example, the statement that AI already outperforms humans in certain tasks, for example, image classification and text comprehension, while the technology still lags behind the capabilities of humans in more complex challenges such as mathematics and visual thinking. The report points out that industry dominates the leading research into AI, and the majority of these companies are located in Silicon Valley. In 2023, industry-led research and development teams developed of total of 51 "remarkable AI models" compared to just 15 from the academic community [6]. The cost of developing leading models such as GPT-4 from OpenAI, which has cost an estimated 78 million dollars, and Gemini Ultra by Google, which has cost some 191 million dollars in computing power, does not just require huge financial resources but also highly sought-after human capital resources in the form of highly trained developers [6]. This is one reason why algorithm development is increasingly industry-led or is done in tandem by science and industry.

Now its 7th edition, the current 2024 report has, for the first time, included a new chapter on "Science and Medicine" which analyzes the increasing use of AI in medical research and clinical practice [6]. Current figures from May 13, 2024 show that the US-Food and Drug Administration (FDA) approved a total of 882 AI-based medical products up until 2023 [7]. Figures showing the changes over time reveal that development has accelerated, with the original figure of just three FDA-approved AI medical products in 2013 rising to a total of 171 in 2023. More recently, 191 new applications were added in the first five months of the current year alone [6].

A review of the distribution of FDA-approved AI-based medical products according to different medical specialties shows that radiology stands out as the AI frontrunner with 671 currently approved applications, followed by cardiovascular medicine with 89 [7]. To date, just one AI-based medical product which was assigned to the field of gynecology and obstretrics has successfully passed the approval process of the FDA. The KIDScore D3 tool supports specialists in reproductive medicine by providing prognoses on the probability of embryos developing, based on their statistical viability [8]. However, more and more AI-based gynecological applications are being submitted to the FDA for approval. The process is fundamentally different from the traditional FDA process used to approve medications and is changing in parallel to the rapid technological developments.



Artificial Intelligence in Gynecology

The AI sessions of the ACOG Annual Clinical and Scientific Meeting 2024 (ACSM) began with a classification of some of the terminology currently widely used by the press (> Fig. 1). While artificial intelligence (AI) includes the concept that machines/algorithms carry out tasks which would normally require human intelligence, Machine Learning (ML) refers to algorithms which learn from patterns and relationships between data, without having been explicitly programmed. ML is divided into three main types: Supervised Learning, which means that the algorithm learns from previously prepared and marked training data; Unsupervised Learning, which means that the algorithm learns from unmarked and unstructured training data and independently discovers relationships within data; and Reinforcement Learning, which includes models that have learned to make decisions through interactions with the environment and associated rewards. Deep Learning is a subdomain of machine learning and uses deep neuronal networks modelled on the human brain, consisting of many sequentially connected layers, which make it possible to detect and model complex patterns and connections in large and often unstructured volumes of data through hierarchical learning and automatic trait extraction. Generative AI, which is currently a very hot topic in the media, includes deep learning models which are also capable of generating texts and audio and video files as well as synthetic data.

After this introduction, various areas of AI application in gynecology and obstetrics are presented below.

Al in fetal heart rate monitoring

The first area covers the use of AI in fetal heart rate (FHR) monitoring. Although standards for evaluating CTGs have been established, for example the FIGO criteria, evaluations are often still in-

consistent and subjective. High intra- and inter-rater variability and uncertainties about the identification of critical conditions can result in risks for mother and infant not being recognized and treated in time [9]. Initially, intelligent algorithms were used to support FHR, but none of them have been able to provide specific predictive prognoses which would lead to the early detection of fetal risks. The core message from the INFANT trial, which was first published in 2017 and included 46 000 patients from 24 centers, was that computer-aided evaluation of CTGs in women who had continuous electronic FHR monitoring during contractions did not lead to an improvement in the clinical outcomes of mothers or babies [10]. This must be set against the harsh criticisms levelled against the study design of the INFANT trial, which include inconsistent randomization and blinding and inadequate collection of crucial clinical data which should serve as important clinical criteria for decision-making in clinical practice.

O'Sullivan et al. summarized the lessons from the INFANT trial in a review article and formulated the challenges of developing robust AI models for FHR monitoring intrapartum [11]. AI models need orientiation to be able to differentiate between pathological and physiological findings, but as this differentiation is usually not "black or white," this still leaves a range of "not-reassuring" findings which make it difficult for ML algorithms to detect patterns in the data. Moreover, large datasets are rare, but they form the basis for developing every AI algorithm. The training data does not include clinical data about follow-up neonatal care or information about the long-term outcomes of neonates. This means that the current training data limits the development of models to such core elements as umbilical cord pH, base excess, lactate, and Apgar scores [12]. The authors demanded that cases should be defined more precisely and data should be segmented and that additional clinical variables and data modalities are included, which would make it possible, in the longer term, to develop tools with explanatory power to support decision-making.

The study by Chiou et al. presented here shows that a combination of AI and FHR monitoring can be successful [9]. The study investigated automated CTG interpretations as a possible solution for improving early detection rates of fetal hypoxia during contractions and reducing unnecessary surgical interventions, thereby improving the overall care of mothers and neonates. Their study used deep learning to reduce the level of subjectivity associated with visual CTG interpretations. Their results showed the feasibility of using deep learning to predict fetal hypoxia based on CTG traces. But it also needs to be pointed out that to improve the robustness of the results, future investigations need to include greater amounts of data and more diverse data from maternity centers from across the world. Such data would have to include different clinical contexts, demographic characteristics and results [13].

The presentation of this area of application ended with the statement that AI has already arrived in FHR monitoring. Future improvements to the models will be based on far more extensive training data which will lead, in the near term, to clinical validation and medical product approval of the respective algorithms, although this will probably happen first in the US-American market. But such models will not replace medical staff because our American colleagues were all agreed on one point: the decision

to carry out clinical interventions must still rest with the medical team of midwife and doctor.

AI in ultrasound

The presentation of the second area of application still focused on obstetrics. Although arriving at an objective reading of FHR remains a challenge, obstetrical ultrasound findings often offer more tangible standards, meaning that there are more areas suitable for developing robust AI models. AI-sensitive tasks in ultrasound include classification (What is this object?), segmentation (Where is the outline of the head?), navigation (How do I get the best image?), quality assessment (Is this image usable?), diagnosis (What is the diagnosis for this image?) and the writing of reports (Please write an ultrasound report). A review by Chen et al. summarized how a combination of AI and ultrasound can support clinicians to diagnose different conditions and diseases [14]. The authors showed how the combination can increase efficacy, reduce the number of misdiagnoses, improve the quality of medical services, and ultimately benefit patients. In obstetrical ultrasound Al is used to recognize structures, e.g, of abdominal organs and facial structures, and to calculate ventricular volumes and ventricular wall thickness in fetal echocardiography. Other applications include automatic measurement of nuchal transparency and volume of fetal structures such as the head. bladder or stomach: classification and diagnosis of the risk of preterm birth using cervical ultrasound; assessment of fetal lung maturity; the detection of congenital heart defects; and the quantification of fetal weight and gestational age. In their systematic review of the literature, lost et al. showed that when medical specialties were compared, the use of AI in gynecological ultrasound was used predominantly in obstetrics, even though there are many other areas where AI could be usefully applied, for example to identify adnexa and breast tumors and to assess the endometrium and pelvic floor [15].

The key message of the session is that AI-guided ultrasound is already a reality, usually operating below our level of awareness as it is seamlessly integrated into the ultrasound unit. According to our colleagues, the benefits of AI-supported ultrasound lie above all in the increased efficiency, for example, faster image capture and evaluation and automatic measurements. Other benefits include improved results due to more consistent evaluations, greater precision, and fewer measurement errors due to standardization as well as support for medical staff by providing training, assisting with knowledge, and reducing processing. But the hurdles to implementation are also mentioned: they are the same problems which were already addressed in the context of AI and FHR monitoring: data is crucial. The development of AI is restricted by the lack of high-quality data and by inherent bias. There are also concerns about data protection and data security. The performance of algorithms remains a challenge as the complex models have to function in real time and their explanatory power and transparency are often insufficient for clinical users. Finally, an appeal was made to the listeners that there would have to be more investment in technological acceptance. Clinical validation is still patchy, there are regulatory obstacles, and the issue of liability needs to be resolved before AI can be extensively adopted in clinical practice [16].

Al in robotic surgery

When presenting the third area of application, our colleagues introduced yet another concept: Surgical Data Science (SDS). SDS is an interdisciplinary field which uses the methods of data science und computer science to improve surgical procedures and outcomes. It consists of the collection, analysis, and interpretation of data from different sources and modalities, including imaging, patient files, intraoperative sensors, and other medical devices [17]. SDS aims to improve surgical planning and preparation by creating more precise and more individualized surgical plans. During surgery, SDS supports the surgeon by offering real-time analysis, which provides important information and can recognize potential problems early on. Data analysis is used to optimize postoperative monitoring and follow-up and recognize complications at an early stage. SDS also contributes to improving surgical training by using virtual reality and simulations based on real data. SDS also supports clinical research by analyzing large volumes of data to obtain new insights into surgical practices and patient outcomes. This means that SDS is closely linked to robotic surgery, which permits the structured collection of objective und granular parameters of surgical performance, e.g., a precise recording of exerted pressure or the length of coagulation phases. As more and more of this data is collected and combined with data processing by AI, SDS can contribute to expanding and automating coaching, feedback, assessment, and decision-making aids in surgery [18].

A familiar pattern emerges with this: if a large, diverse, multimodal dataset is available which cannot be independently processed by humans due to numerous different variables, artificial intelligence is able to collect valuable data treasures, whose location was previously unknown. After data treasures have been collected, this can be used to gain knowledge or, based on the learned relationships within the data, AI can be used to provide support to treating medical staff carrying out surgical procedures. It became clear during the presentation of the third area of application that AI has also entered the surgical field, even if currently it is only present in areas which permit the collection of structured data, i.e., mainly robotic surgery [17]. Given that surgical robots are not yet part of the standard equipment of operating rooms and when they are present, the robot might currently be used by other colleagues from urology to carry out robot-assisted prostatectomy procedures, it remains to be seen when SDS and AI will become standard companions in gynecological and obstetrical procedures.

Generative Al

The second session was entirely devoted to a single subset of AI: generative AI. Since the official market launch of the large language model (LLM) ChatGPT by OpenAI, a company which is headquartered in San Francisco, generative AI has experienced an explosion of media interest. Such so-called Foundation Models use vast amounts of data which are trained up through Reinforcement Learning and Supervised Learning and human feedback to process texts, data, language, and other structured data and carry out many different tasks. Potential tasks include the extraction of information, image descriptions, object recognition, analysis of psychological moods, and finding answers to many different questions. Previously, AI required the development of a specific model for a specific task. Today, however, an appropriate Foundation Model can undertake numerous tasks at the same time. LLMs make use of mathematical models, for example to calculate the next most probable word when formulating texts. Kiela et al. showed the speed at which these AI systems have outperformed humans in recent years in language and image recognition and that the breakthrough occurred in the last 3–4 years [19]. Nori et al. expanded these findings to include medicine and showed how specialized medical LLMs are rapidly increasing their capacities and capabilities [20]. The session summarized the current status of generative AI under the title "The Good, the Bad and the Ugly" without discussing concrete applications in gynecology and obstetrics (**> Fig. 2**).

Generative AI already offers benefits in many relevant areas of medicine which range from clinical care to simplifying administration, supporting carers and patients to medical teaching and research and public health. On the other hand, "The Bad" shows that many of the issues of generative AI are still unsolved, including the problem of ensuring proper data protection, the lack of transparency of decisions for users, and the ethical and legislative basis. It is therefore still unclear how issues such as intellectual property, liability, and copyright laws should be dealt with in the context of generative AI and who will have access to specific models. Questions relating to the effects of the clinical adoption of models also remained largely unanswered. In which areas can we expect to see a decline in human capabilities with avoidance of previously unavoidable learning processes in medical training? Will the implementation of AI lead to "de-humanization" in certain areas? "The Uqly" shows how dangerous the weaknesses of generative AI can be. Examples include so-called "hallucinations," when generative AI models simply make up information so that they can provide an answer "by hook or crook," and "omissions," when the model does not provide a complete answer and withholds important information. A study by Alkaissi et al. investigated the ability of ChatGPT to describe the pathogenesis of different diseases and was able to show that at times, the chatbot hallucinated non-existing pathogenic relationships or invented sources which did not exist [21]. LLMs have also been shown to have a tendency to manifest prejudices and discrimination although as researchers, we cannot be held entirely blameless for this. This is because models are trained on existing databases which can include significant ethnic and gender-specific biases. Zack et al. was able to show that GPT-4 did not model the demographic range of diseases correctly and consistently produced clinical vignettes which stereotyped demographic presentations [22]. The authors emphasized that it was urgently necessary to carry out a detailed and transparent evaluation of the biases in the instruments of generative AI with regards to planned cases of application before they are integrated into clinical care. The guality and safety of publicly available models is currently not good enough to ensure the safe handling of sensitive patient data. The models still struggle with performance problems in terms of precision and with a lack of knowledge-based thinking and argumentation which can lead to misinformation. In some cases, this can feed into so-called "deep fakes" which are often difficult to recognize by the human eye due to the high visual and textual capability

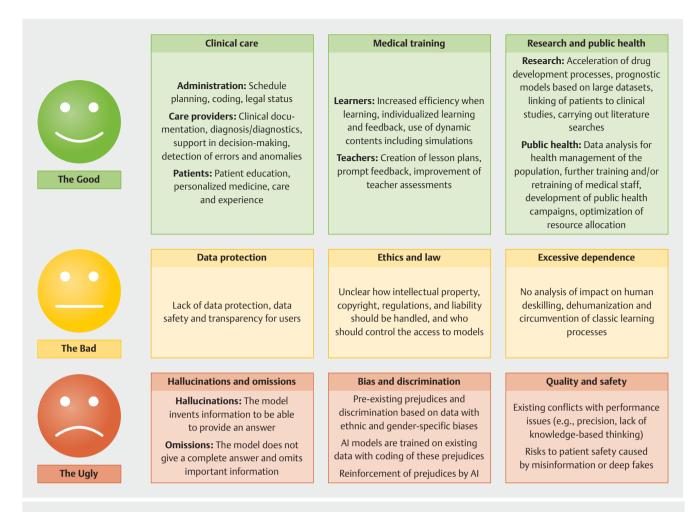


Fig. 2 Overview of The Good, the Bad and the Ugly of Generative AI (Fig. is based on data from: summary of the session "Generative AI" of the 2024 ACSM).

of the models. Containment strategies such as those proposed by the Trustworthy & Responsible AI Network (TRAIN) [23], the Coalition for Health AI [24] and the AI Act of the European Union [25] are important steps on the way to defining basic rules and boundaries for AI.

The session ended with an important note for the auditorium: generative AI is becoming an increasingly powerful tool which is used by patients, medical staff, and family members. For us as specialists for gynecology and obstetrics, this means that we should not miss the historical opportunity to look at these applications in detail, evaluate them critically, and actively contribute to integrating them in our specialist field.

Conclusion and Outlook: Artificial Intelligence and Gynecology and Obstetrics, quo vaditis?

In summary, the impressions we obtained in Silicon Valley and at the ACSM can be condensed into three main points which explain why AI will find its way into gynecology and obstetrics and how it is already changing clinical practice or will change it in the near future:

The data

"Data is the new oil" is a metaphor coined by the mathematician Clive Humby in 2006 which is now more relevant than ever. "Big Data" is also present in gynecology. In gynecological oncology, for example, the growing flood of data obtained through advances in precision oncology, better genomic profiling and targeted therapies has resulted in significant improvements in diagnosis and treatment, which has led to significant breakthroughs [26]. These advances are accompanied by an abundance of multimodal therapeutic and diagnostic data alongside increasingly complex research results which, little by little, are exceeding the limits of human cognitive processing. Al is already helping to expand human medical intelligence to successfully process these huge volumes of data and text information [27,28]. And yet: although some areas have an abundace of data, other areas such as fetal heart rate monitoring show that while AI has potential, there is still not enough high-quality training data with the corresponding level of diversity that would be necessary to develop robust models.

The visual aspect

The rapid development of FDA-approved medical AI products in radiology shows: AI has already proven to have a special talent for processing visual elements [6]. And such visual data is also available in gynecology: from mammographies and histopathological data to colposcopies and laparoscopies to specialized prenatal ultrasound, AI is learning to process different visual components used in gynecological diagnostics. Although performance can still vary significantly depending on the specific application, these areas are creating the first bridges over which the technology will enter into our specialist field.

The patient

As the discussion focuses on AI in obstetrical and gynecological diagnostics and treatment, it is important not to lose sight of the patients. The mean age of primipara in Germany is 31.7 years, and gynecology treats the full age range of patients, including a not insignificant number of younger, digitally-savvy patients [29]. This will contribute to emerging technologies rapidly becoming more relevant for treatment in clinical reality.

The overview of the two AI sessions at the 2024 ACSM shows that possible applications of artificial intelligence (AI) are very diverse and so extensive that they cannot be comprehensively summarized in a short review. With AI finding increasing applications in clinical care, including in gynecology, scientific monitoring will be needed. Whether it takes the form of original scientific works or the synthesis of evidence using structured literature reviews and meta-analyses, when technological developments happen so fast, this can only be done through interdisciplinary global networks. To that end, the Commission Digital Medicine of the DGGG has positioned itself nationally in Germany and will be expanding its activities in future to work towards making current issues accessible for its own specialist association and to use the potential of AI to improve gynecological and obstetrical care.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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