Odon's Device: A Novel Innovation in Assisted Vaginal Birth

Ms. Sherlin Sapthica.R[1], Ms. Sasirekha[2], Ms, Aruna.R.[3]
[1]*Asso. Professor, Dept of Obstetrics and Gynecological Nursing, Ganga College of Nursing, Coimbatore*
[2]*Professor., Dept of Community health Nursing, Ganga College of Nursing, Coimbatore*
[3]*Asso. Professor, Dept of Medical and Surgical Nursing, Ganga College of Nursing, Coimbatore*

Abstract- Odon's Device represents a transformative advancement in assisted vaginal birth, providing a safer and less invasive alternative to conventional instruments such as forceps and vacuum extractors. Developed by Jorge Odon and refined through global clinical research, the device uses a soft polyethylene sleeve that gently grips the fetal head via an inflatable mechanism. This article reviews its development, design, mechanism, clinical trials, advantages, challenges, ethical considerations, and future prospects. Preliminary clinical trials have shown promising safety and efficacy profiles, indicating the device's potential to reduce maternal and neonatal trauma while increasing accessibility to safe operative vaginal births, particularly in low-resource settings.

I.INTRODUCTION

Assisted vaginal birth is a critical intervention that helps safely deliver babies when spontaneous vaginal delivery faces challenges. Globally, complications during the second stage of labour contribute significantly to maternal and neonatal morbidity and mortality. While forceps and vacuum extractors have been mainstays in managing difficult deliveries, they require highly skilled operators and carry risks including perineal trauma, fetal scalp injuries, and intracranial hemorrhage. These factors have limited their availability and use, especially in low- and middle-income countries (LMICs). The development of Odon's Device promises to bridge this gap by providing a simpler, safer, and more accessible method for operative vaginal delivery.

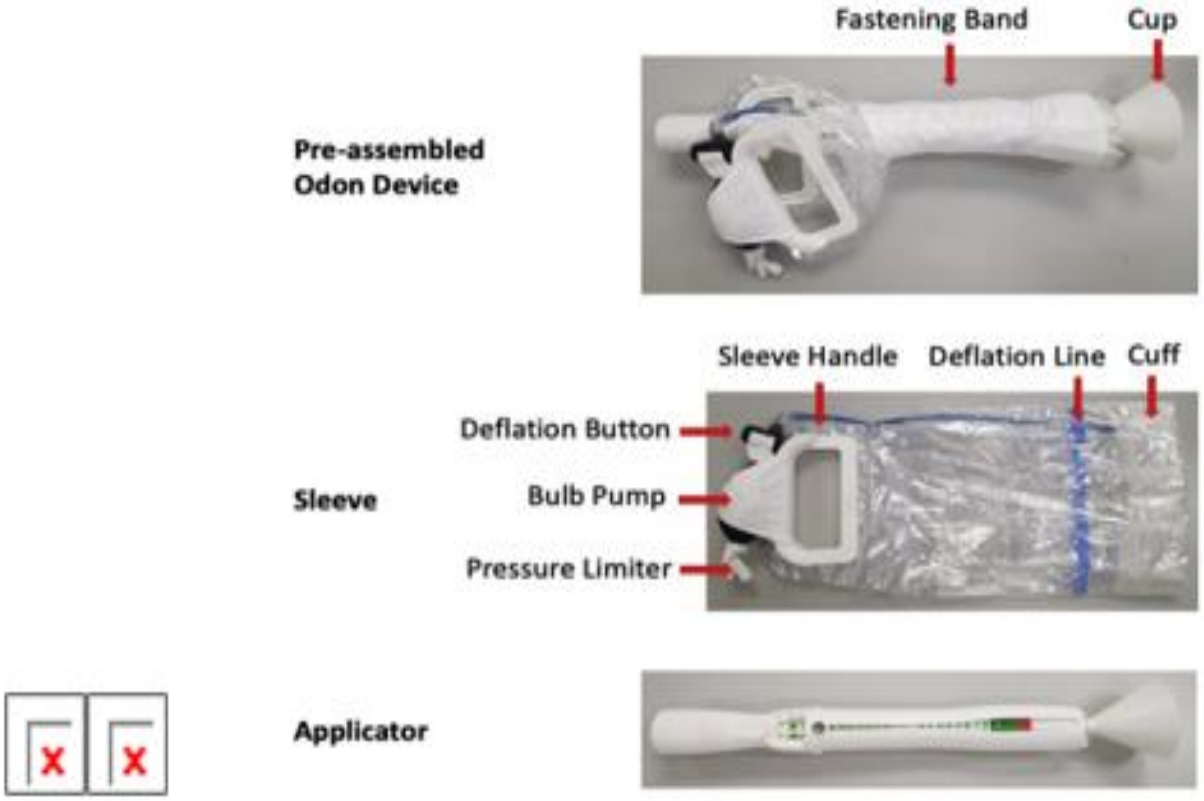
II.HISTORICAL BACKGROUND

The inception of Odon's Device stands out as a remarkable example of innovation inspired by everyday observations. Jorge Odon, an Argentine car mechanic without formal medical training, conceptualized the idea after witnessing a simple trick in which a plastic bag is used to extract a cork from a bottle. This imaginative approach translated into the concept of a device that could gently assist a baby's passage through the birth canal by enveloping the fetal head with a soft, inflatable sleeve. Once the idea was shared with medical experts and the World Health Organization (WHO), multidisciplinary teams of engineers, obstetricians, and public health professionals worked collaboratively to refine the device's design. Since its development, the device has undergone multiple phases of testing—ranging from laboratory simulations to early clinical feasibility studies conducted in Argentina, South Africa, and other countries. These trials evaluated safety, ease of use, and clinical outcomes, laying the foundation for larger randomized controlled trials currently underway. The unique origin of Odon's Device highlights how innovation can emerge from unconventional sources and how global partnerships can accelerate translation into clinical practice.

III.DESIGN AND COMPONENTS

Odon's Device features a thoughtfully engineered design that aims to balance efficacy, safety, and ease of use. Its primary component is a soft, flexible polyethylene sleeve designed to fit snugly around the fetal head within the birth canal. Unlike rigid forceps blades, this sleeve applies gentle, uniform pressure when inflated, thereby minimizing the risk of focal trauma to fetal tissues and maternal soft tissues. The device includes a specially designed applicator that facilitates smooth insertion and correct placement of the sleeve without causing maternal discomfort or

injury. After placement, the applicator allows controlled inflation of a circumferential air chamber that secures the grip on the fetal head. The device's traction handle then enables the clinician to apply gentle, steady traction in line with uterine contractions to assist delivery. Importantly, Odon's Device is intended for single-use, sterile packaging, reducing the risk of cross-contamination and infection. The lightweight, portable, and disposable nature of the device enhances its suitability for diverse clinical environments, including resource-limited settings where sterilization capacity may be constrained.



IV.MECHANISM OF ACTION

The operational principle of Odon's Device involves enveloping the fetal head in a soft sleeve that is inflated to achieve secure but gentle adherence. Once the cervix is fully dilated and the fetal head is well engaged, the clinician inserts the applicator with the deflated sleeve around the fetal head. The air chamber is then inflated to create a uniform grip, distributing traction forces evenly rather than concentrating pressure at discrete points as occurs with forceps blades or vacuum extractor cups. After inflation, the applicator is removed, leaving the sleeve in place. During maternal contractions, the clinician applies gentle traction using the handle, guiding the fetal head smoothly through the birth canal. This approach reduces the likelihood of maternal soft tissue injuries, such as severe perineal tears, and minimizes neonatal scalp trauma and intracranial pressure fluctuations. After delivery of the head, the sleeve is deflated and removed prior to the delivery of the shoulders and body, ensuring no obstruction. By avoiding the use of rigid metal components and negative pressure suction, the device presents a novel mechanism designed to improve the safety profile of operative vaginal births.

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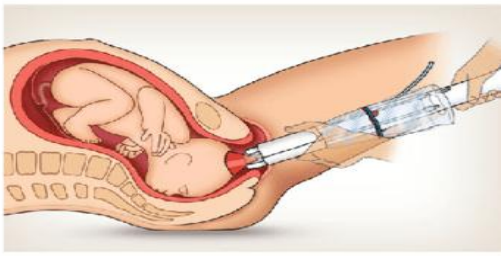
The inserter is applied on the head of the baby. A soft plastic bell assures perfect adaptation to the fetal head and prevents damage.



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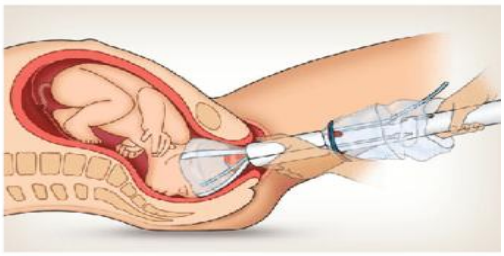
The inserter progressively positions the Odón device around the head of the baby. Positioning occurs as the inserter gently produces the sliding of the two surfaces of the folded sleeve along the birth canal and around the baby's head.



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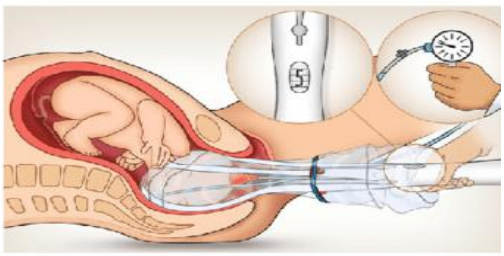
When the Odón device is properly positioned, a marker on the insertion handle become clearly visible in the reading window. A minimal and self-limited amount of air is pumped into an air chamber in the inner surface.



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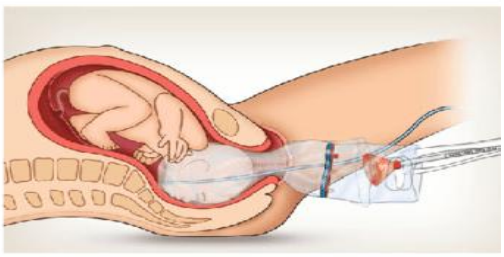
This produces a secure grasp around the head of the baby that fixes the inner surface and allows for traction. The inserter is removed.



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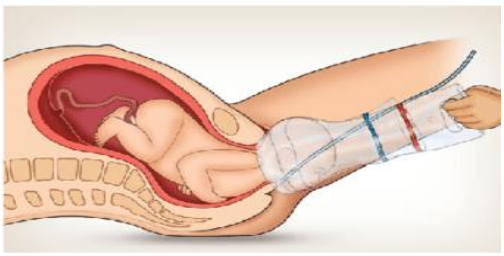
The head is delivered taking advantage of the sliding effect of the two surfaces of the folded sleeve. Lubrication of the surfaces further facilitates the extraction process. If needed, traction can be applied up to 19 kg (which is equivalent to the force applied with the metal vacuum extractor).



V.CLINICAL EVIDENCE AND TRIALS

Preliminary clinical evidence supporting Odon's Device has been encouraging. Initial phase I and II studies conducted in countries such as Argentina and South Africa have demonstrated the device's feasibility and safety. These early trials reported successful placement rates, minimal maternal perineal trauma, and a low incidence of neonatal scalp injuries or hematomas compared to traditional vacuum extraction and forceps deliveries. Importantly, the device showed high acceptability among both clinicians and mothers, with many praising its less intimidating appearance and perceived gentleness. Further, early data suggest a potentially shorter learning curve, indicating that healthcare workers with limited operative vaginal delivery experience may acquire proficiency faster than with conventional instruments. Large multicenter randomized controlled trials led by the WHO are currently in progress across

various settings, including India, Kenya, and Nigeria, aiming to rigorously compare maternal and neonatal outcomes with those of forceps and vacuum extractions. These studies will provide high-quality evidence regarding the device's effectiveness, safety, and applicability in diverse populations and clinical scenarios.

Advantages

Odon's Device offers several compelling advantages that could revolutionize the practice of assisted vaginal birth. First and foremost, the device is designed to reduce trauma by distributing traction forces evenly around the fetal head, which helps minimize maternal perineal injury and neonatal scalp and brain trauma. This is a significant advancement compared to the focal pressure exerted by traditional forceps and vacuum extractors. Second, the device's simple design and ease of use could democratize operative vaginal delivery, making it accessible to midwives, nurses, and general practitioners in addition to obstetricians. This broader accessibility has important implications for expanding access to safe delivery assistance, especially in low-resource settings with limited specialist availability. Third, the device's single-use sterile packaging reduces the risk of infection, an important consideration in many clinical environments. Fourth, its portable and disposable nature facilitates use in a variety of settings, including rural clinics and home birth scenarios. Finally, the device's less intimidating appearance compared to metal instruments may improve maternal comfort and acceptance, potentially reducing anxiety during labour and delivery.

VI.CHALLENGES AND LIMITATIONS

Despite its promising potential, Odon's Device faces several challenges and limitations. Currently, the device is undergoing clinical validation and has not yet achieved widespread regulatory approval. The limited availability restricts its immediate use to clinical trial settings. Additionally, while early studies are encouraging, comprehensive data from large-scale randomized controlled trials are needed to conclusively establish the device's safety and effectiveness. Some obstetricians express caution regarding device insertion in advanced fetal descent or unusual fetal positions, where the sleeve may be difficult to place correctly or may fail to provide adequate traction. Cost considerations also play a role, especially for widespread implementation in low-income countries where budgets are constrained. There is a need for clear guidelines delineating clinical indications and contraindications to prevent inappropriate use. Training and continuous quality assurance programs must be developed to ensure providers use the device competently and safely. Finally, long-term neonatal follow-up is required to assess potential neurological outcomes following device-assisted delivery.

VII.ETHICAL AND PRACTICAL CONSIDERATIONS

Introducing a novel obstetric device into clinical practice necessitates rigorous ethical oversight. Informed consent is essential, particularly when the device is used within clinical trials or in settings where its safety profile is still being established. Providers must be adequately trained to ensure appropriate patient selection and proper device usage, minimizing risks associated with misuse. Ethical considerations also include equitable access, ensuring that underserved populations benefit from innovation rather than being excluded. Continuous monitoring and transparent reporting of adverse events and outcomes are vital to maintaining public trust. Additionally, patient autonomy should be respected by providing clear information about the device, its benefits, risks, and alternatives. Implementing the device in accordance with international guidelines and local regulatory standards will support ethical and safe integration into maternal health services.

Comparative Analysis with Traditional Instruments

Forceps and vacuum extractors have well-established efficacy but also documented adverse effects. Forceps apply mechanical pressure directly to the fetal head and maternal soft tissues, increasing the risk of vaginal and perineal lacerations, pelvic floor damage, and fetal facial nerve injury. Vacuum extractors reduce maternal tissue trauma but may cause neonatal scalp abrasions, cephalohematoma, and intracranial hemorrhage due to negative pressure.

Odon's Device, by contrast, uses an air-inflated sleeve that gently embraces the fetal head, distributing traction forces evenly without applying focal pressure. Unlike metal instruments, it is flexible, which lowers soft tissue trauma risk. Its single-use design minimizes infection risk inherent in reusable tools. Early evidence indicates that the device may reduce the incidence of both maternal and neonatal injuries, but larger trials are ongoing to establish these findings statistically.

Training and Skill Transfer

A major barrier to the wider adoption of assisted vaginal birth is the steep learning curve for forceps and vacuum use. Training often requires prolonged supervised practice and institutional support. Odon's Device, with its straightforward application technique, has the potential to democratize the ability to perform safe assisted deliveries. Simulation training modules can rapidly build competency among midwives, nurses, and general practitioners. This scalability is crucial in settings where obstetricians are scarce.

WHO and other global health partners are developing standardized training curricula and competency checklists to facilitate safe device deployment. Remote training via telemedicine and video demonstrations may also support capacity building in rural and underserved areas.

Implementation in Low-Resource Settings

In many LMICs, lack of access to safe operative delivery contributes to high rates of maternal deaths from obstructed labour, uterine rupture, and birth asphyxia. The Odon Device's affordability, portability, and ease of use make it a promising tool to improve outcomes in these settings. It may also reduce the reliance on emergency cesarean sections, which often carry greater risks due to limited surgical infrastructure and postoperative care.

Successful implementation will require integration into existing maternal health frameworks, supply chain logistics, and ongoing quality assurance systems. Engagement with local healthcare workers, governments, and communities is essential to ensure acceptability and appropriate use.

Global Health Impact and Policy Considerations

If proven effective and safe through large-scale trials, Odon's Device could become a key component of global initiatives aimed at reducing maternal and neonatal mortality. Organizations such as WHO, UNFPA, and various NGOs may incorporate it into guidelines and funding programs. Policymakers will need to consider regulatory approvals, training requirements, cost-benefit analyses, and monitoring frameworks to facilitate broad adoption.

VIII.FUTURE PROSPECTS

The future outlook for Odon's Device is promising, contingent upon the outcomes of ongoing clinical trials and regulatory approvals. If demonstrated to be safe, effective, and cost-efficient, the device may become an integral component of global obstetric care. It holds particular promise for improving maternal and neonatal outcomes in resource-limited settings where skilled operative vaginal delivery is currently unavailable. Future innovations may include refinements in device materials and design to enhance comfort and ease of use. Development of comprehensive training packages, including simulation-based education and telemedicine-supported mentorship, will facilitate widespread adoption. Integration into global maternal health programs, supported by agencies such as the WHO, UNFPA, and UNICEF, could accelerate access in LMICs. Long-term research will continue to explore neurological outcomes, device performance in complex deliveries, and cost-benefit analyses to optimize utilization. Ultimately, Odon's Device has the potential to significantly reduce global maternal and neonatal morbidity and mortality related to obstructed or complicated labour.

IX.CONCLUSION

Odon's Device represents a groundbreaking innovation in the field of assisted vaginal birth, offering a safer and more accessible alternative to traditional instruments such as forceps and vacuum

extractors. By employing a gentle, inflatable polyethylene sleeve to uniformly grip the fetal head, the device has the potential to significantly reduce maternal and neonatal trauma. Early clinical evidence demonstrates promising safety and efficacy, while its simple design facilitates easier training and broader use, particularly in low-resource settings where access to skilled obstetric care is limited. Despite some challenges related to regulatory approval, cost, and the need for comprehensive clinical validation, Odon's Device holds immense promise for improving global maternal and neonatal outcomes. With continued research, ethical implementation, and integration into healthcare systems, this novel tool may soon become an essential component of safe childbirth worldwide.

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