Amniotic membrane and amniotic fluid dressing for treating diabetic chronic non-healing ulcers patients – A hospital-based experience from Kolkata.

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ABSTRACT

Introduction:
Human amniotic membrane and amniotic fluid applications represent recent advancements in cell therapy and regenerative medicine. The use of autologous skin grafts, AquaCell Ag+ (silver) dressings, hyperbaric oxygen therapy, bioengineered skin, negative pressure wound therapy, cultured epidermal cells (EpiCell), micronized dried amniotic membrane, amnion cytokine extract, and amniotic membrane are highly effective but come at a significant cost. Freshly collected amniotic fluid and amniotic membrane contain angiogenic and pro-apoptotic factors that significantly promote epithelialization. The study aims to cure the chronic non-healing ulcers using freshly collected amniotic membrane and amniotic fluid

Methods:
Consent and Collection Preparation: Informed consent was obtained from the donor mother undergoing a caesarean section, by ethical guidelines. Amniotic Membrane Collection: Immediately after the delivery of the baby and placenta, the amniotic membrane was separated from the placenta. It was carefully peeled away from the chorion and washed with sterile saline to remove blood and other contaminants. The membrane was then stored in a sterile container with an appropriate medium. Amniotic Fluid Collection: Amniotic fluid was aspirated during delivery using a sterile syringe and immediately transferred into a sterile container for application. Both the amniotic fluid and membrane underwent screening for infections (e.g., HIV, hepatitis, syphilis) and bacterial contamination to ensure safety for therapeutic use. Freshly collected amniotic membranes and fluids were used within an hour as dressings for chronic non-healing ulcers in 27 patients at a hospital in Kolkata. The amniotic membrane and fluid were applied every seven days, with the procedure repeated and observations recorded. Statistical analysis was conducted using Friedman's ANOVA with multiple comparisons.

Results:
In this study, 27 patients with chronic non-healing ulcers of various etiologies were observed in a hospital. Amniotic membrane and amniotic fluid dressings were applied every seven days, with the procedure repeated at each visit. The mean ulcer depth in the study group progressively decreased with each observation. Statistical analysis showed a significant reduction in mean ulcer depth ($p < 0.001$) at each visit. By the end of the 12th week, 25 patients (92.59%) had fully healed, while 2 patients (7.41%) showed gradual improvement. Ultimately, the two unhealed cases recovered over a longer period with continued amniotic membrane and fluid dressings. The study also assessed the rate of healing promotion, improvement in pain-free walking, and disability prevention by reducing the need for amputation. Additionally, angiogenesis was evaluated to ensure proper wound healing, emphasizing the importance of utilizing amniotic fluid and membranes in hospitals to prevent unnecessary waste.

Conclusion:
In conclusion, this study demonstrates that amniotic membrane and fluid dressings are highly effective in reducing ulcer dimensions and significantly contribute to successful healing with positive clinical outcomes in humans.