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Use of a Novel Hemostatic Agent in Control of Traumatic Bleeding in Damage Control Surgery

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Traumatic injury has become commonplace in today's society. Better weaponry, along with high speed motor vehicle accidents/blunt trauma has allowed for significant morbidity and mortality in our trauma patients. Damage control surgery techniques have predominated management of such patients, but mortality remains high in the face of significant and severe acute hemorrhagic shock. Along with truncated operative techniques, hemostatic agents remain critical in assisting in control of such hemorrhage.

At present, blood product availability remains at an all-time low. Given this, alternatives to utilization of blood products remains critical to provide patients' opportunities for survival. In this study, we aim to demonstrate use of a novel hemostatic agent, in an off-label use in damage control surgery in abdominal trauma. The product, which is an etherified cellulose product that is pH neutral, has great utility with severe topical bleeding. The product provides excellent hemorrhage control in patients with severe bleeding in burn surgery, while demonstrating and extreme safety profile.

In severe trauma, the patient who presents to the trauma bay in extremis has activation of mass transfusion protocols in the Emergency Department (ED) to allow for establishment of hemodynamic normality to provide an opportunity for movement to the operative theater. As the patients move from the ED to the operating room, mass transfusion continues through the operative intervention, which is truncated in damage control surgery to minimize operative time and blood loss. In many such instances, significant volumes of resuscitative fluids are administered, with crystalloid, PRBC's, FFP, platelets, and cryoprecipitate allow for third spacing of fluids along with loss of abdominal domain as hemorrhage control is achieved. In many instances, the abdominal cavities of such patients are managed with negative pressure wound therapy (NPWT) to attempt to control such loss of domain, and facilitate control of edema. The resuscitation then moves to the ICU setting, with continued utilization of blood products. The vicious cycle of continued bleeding, blood product utilization and further bleeding, along with an already cold and coagulopathic patient allows for the death of the patient in many instances.

In this study, we aim to control the initial source of bleeding during the operative intervention with the off-label use of a novel hemostatic agent. In achieving rapid hemorrhage control in the operative theater with the use of the novel product, this study has identified decreased intra-operative blood product utilization and decreased operative time, along with decreased post-operative blood product utilization. In the rapid control of such hemorrhage, and with the reduction of blood product utilization, the complications of loss of domain and subsequent inability to close the abdominal cavities of these patients was reduced. Moreover, overall blood product utilization was reduced during the pre/intra and post- operative periods, allowing for rapid return to the operating room for completion of the truncated operative interventions. Overall, this has allowed for rapid closure of patient abdomens, with reduction of ventilator days, ICU stay, and overall hospital LOS.

Objectives

1) Explain damage control surgery principals
2) Review current hemorrhage control pitfalls
3) Identify use of novel hemostatic agent and in off-label use in control of hemorrhage
4) Identify outcome of use of such agent in regards to abdominal closure, reduction of blood product utilization, reduction of ventilator days, reduction of ICU days and reduction of overall hospital LOS

Main Clinical Observation Indicators

	control	eCMC	p-Value
Pre-Op Blood (ml)	1180.13	1310.75	>0.05
Intra-Op Blood (ml)	1222.67	570.5	<0.05
Intra-Op PRBC (ml)	621.1	326.3	0.0281
Post-Op Blood (ml)	353	380.07	>0.05
Closure Time (hrs)	30.57	21.62	0.065
Time in ICU (days)	10.75	9.2	0.5971
Length of Stay (LOS)(days)	13.94	13.11	0.7965
New Injury Severity Score (NISS)	15.17	29.7	0.0064
Injury Severity Score (ISS)	13.56	21.45	0.0428
Trauma and Injury Severity Score (TRISS)	0.8731	0.8035	0.4752

Conclusions

- ISS and NISS demonstrated significantly worse injuries in study group with eCMC ($p < 0.0064$).
- While pre-operative and post-operative blood use were unchanged, intra-operative blood utilization was reduced ($p < 0.02$).
    - 53% reduction in overall intra-operative blood utilization
- Time to closure of abdomen was not statistically different ($p<0.06$), but time to closure was significantly reduced in study group.
    - 21.62 hrs in study group vs. 30.57 hrs in control group
- ICU LOS and overall LOS were reduced marginally:
    - ICU LOS: 9.2 days in study group vs. control of 10.75 days
    - Overall LOS: 13.11 days in study group vs. control of 13.94 days
        - No statistical difference.
        - Cost savings overall from reduction of stay.
        - Need larger cohort.
- No major adverse events.
    - No intra-abdominal infections identified in study group
        - Follow up CT abdomen of study patients with no intra-abdominal abscess
- Ease of use.
    - Place in abdomen with laparotomy pads.
    - “Remove” on second look operation.
    - No residual as compared to other hemostatic agents.
        - No worry of retained foreign body

References

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