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ADDENDUM



Price JS, Tackett S, Patel V. Observational evaluation of outcomes and resource utilization from hemostatic matrices in spine surgery. J Med Econ 2015; 1-10.

The authors have been made aware that some assumptions made in regards to certain surgical case data gaps require further clarification than noted in the paper. We hope this clarification not only assists the reader to better appreciate the methodology used in this article, but also note it allows the authors a chance to more accurately portray an estimation error in regards to product used, however minor this change is. None of the other study results are affected by this change and the conclusions of the study remains the same.

The edits to the Patients and Methods, Results, Table 3 and Table 4 are as follows:

TABLE 3. Results of Group A

Current version

Comparative Outcomes	FLOSEAL only (reference group) compared to SURGIFLO only			
	FLOSEAL (N = 12,783)	SURGIFLO (N = 1,531)	Odds Ratio (95% CI) ^a /Adjusted Difference ^b	<i>p</i> -Value ^d
Complications: n(%) ^e				
Blood Loss Related Complications	928(7.3)	80(5.2)	1.10(0.86 -1.43)	0.44
Severe Complications	200(1.6)	19(1.2)	0.74 (0.44-1.25)	0.26
Other Complications	464(3.6)	50(3.3)	0.99 (0.72-1.35)	0.94
Transfusion: n(%) ^e				
Any transfusions	365(2.9)	47(3.1)	2.56 (1.79-3.65)	< 0.0001
Day 1 transfusions	143(1.1)	14(0.9)	1.58 (0.87-2.89)	0.13
Day 2-4 transfusions	250(2.0)	37(2.4)	3.3 (2.2-4.98)	< 0.0001
Any PRBC transfusions	346(2.7)	43(2.8)	2.54 (1.75-3.67)	< 0.0001
Hospital LOS (days): Mean (95% CI) ^b	2.8(2.7-2.8)	2.7(2.5-2.8)	-0.11 days	0.06
Surgery Time (min): Mean (95% CI) ^b	190(187-193)	199(194-203)	8.84 min	< 0.0001
Amount Product Used (mL): Mean (95%CI) ^b	7.6 (7.5-7.8)	11(10.6-11.4)	3.35 mL	< 0.001

^aOdds ratios from logistic regression for all binary outcome variables

^bRatios and adjusted mean value for each group from GLM Negative binomial regression analyses

Relative risk converted from adjusted odds ratio and percentage of event in each group

^dP-value from logistic regressions or GLM

^eN(%) from unadjusted frequency tables

Abbreviations: CI = confidence interval; LOS = length of stay; min = minutes; N = number of cases; PRBC = Packed Red Blood Cells

TABLE 3. Results of Group A

Corrected version:

Comparative Outcomes	FLOSEAL only (reference group) compared to SURGIFLO only			
	FLOSEAL (N = 12,783)	SURGIFLO (N $=$ 1,531)	Odds Ratio (95% CI) ^a /Adjusted Difference ^b	<i>p</i> -Value ^d
Complications: n(%) ^e				
Blood Loss Related Complications	928(7.3)	80(5.2)	1.10(0.86 -1.43)	0.44
Severe Complications	200(1.6)	19(1.2)	0.74 (0.44-1.25)	0.26
Other Complications	464(3.6)	50(3.3)	0.99 (0.72-1.35)	0.94
Transfusion: n(%) ^e				
Any transfusions	365(2.9)	47(3.1)	2.56 (1.79-3.65)	< 0.0001
Day 1 transfusions	143(1.1)	14(0.9)	1.58 (0.87-2.89)	0.13
Day 2-4 transfusions	250(2.0)	37(2.4)	3.3 (2.2-4.98)	< 0.0001
Any PRBC transfusions	346(2.7)	43(2.8)	2.54 (1.75-3.67)	< 0.0001
Hospital LOS (days): Mean (95% CI) ^b	2.8(2.7-2.8)	2.7(2.5-2.8)	-0.11 days	0.06
Surgery Time (min): Mean (95% Cl) ^b	190(187-193)	199(194-203)	8.84 min	< 0.0001
Amount Product Used (mL): Mean (95%CI) ^b	8.9 (8.7-9.1)	10.8(10.5-11.2)	1.90 mL	< 0.0001

^aOdds ratios from logistic regression for all binary outcome variables

^bRatios and adjusted mean value for each group from GLM Negative binomial regression analyses

^cRelative risk converted from adjusted odds ratio and percentage of event in each group

^dP-value from logistic regressions or GLM

^eN(%) from unadjusted frequency tables

Abbreviations: CI = confidence interval; LOS = length of stay; min = minutes; N = number of cases; PRBC = Packed Red Blood Cells

TABLE 4. Results of Group B

Current version:

Comparative Outcomes	FLOSEAL only (reference group) compared to SURGIFLO only			
	FLOSEAL (N = 2,837)	SURGIFLO (N $=$ 174)	Odds Ratio (95% Cl) ^a /Adjusted Difference ^b	<i>p</i> -Value ^d
Complications: N(%) ^e				
Blood Loss Related Complications	527(18.6)	21(12.1)	0.81 (0.50-1.32)	0.40
Severe Complications	196(6.9)	7(4.0)	0.62 (0.28-1.40)	0.25
Other Complications	196(6.9)	12(6.9)	0.98 (0.52-1.84)	0.94
Transfusion: N(%) ^e				
Any transfusions	331(11.7)	17(9.8)	1.42 (0.82-2.46)	0.21
Day 1 transfusions	189(6.7)	5(2.9)	0.66 (0.26-1.67)	0.38
Day 2-4 transfusions	218(7.7)	11(6.3)	1.60 (0.82-3.12)	0.17
Any PRBC transfusions	320(11.3)	15(8.6)	1.28 (0.72-2.28)	0.41
Hospital LOS (days): Mean (95% CI) ^b	4.4(4.2-4.6)	4.3(3.9-4.8)	-0.12 day	0.57
Surgery Time (min): Mean (95% Cl) ^b	266(258-273)	293(276-311)	26.94 min	< 0.001
Amount Product Used (mL): Mean (95%CI) ^b	10.2(9.7-10.7)	11.7(10.5-13)	1.52 mL	0.008

^aOdds ratios from logistic regression for all binary outcome variables

^bRatios and adjusted mean value for each group from GLM Negative binomial regression analyses

^cRelative risk converted from adjusted odds ratio and percentage of event in each group

^dP-value from logistic regressions or GLM

^eN(%) from unadjusted frequency tables

Abbreviations: CI = confidence interval; LOS = length of stay; min = minutes; N = number of cases; PRBC = Packed Red Blood Cells

TABLE 4. Results of Group B

Corrected version:

Comparative Outcomes	FLOSEAL only (reference group) compared to SURGIFLO only				
	FLOSEAL (N = 2,837)	SURGIFLO (N $=$ 174)	Odds Ratio (95% Cl) ^a /Adjusted Difference ^b	<i>p</i> -Value ^d	
Complications: N(%) ^e					
Blood Loss Related Complications	527(18.6)	21(12.1)	0.81 (0.50-1.32)	0.40	
Severe Complications	196(6.9)	7(4.0)	0.62 (0.28-1.40)	0.25	
Other Complications	196(6.9)	12(6.9)	0.98 (0.52-1.84)	0.94	
Transfusion: N(%) ^e					
Any transfusions	331(11.7)	17(9.8)	1.42 (0.82-2.46)	0.21	
Day 1 transfusions	189(6.7)	5(2.9)	0.66 (0.26-1.67)	0.38	
Day 2-4 transfusions	218(7.7)	11(6.3)	1.60 (0.82-3.12)	0.17	
Any PRBC transfusions	320(11.3)	15(8.6)	1.28 (0.72-2.28)	0.41	
Hospital LOS (days): Mean (95% CI) ^b	4.4(4.2-4.6)	4.3(3.9-4.8)	-0.12 day	0.57	
Surgery Time (min): Mean (95% CI) ^b	266(258-273)	293(276-311)	26.94 min	< 0.001	
Amount Product Used (mL): Mean (95%CI) ^b	11.8(11.3-12.4)	11.7(10.5-13)	-0.13 mL	0.8225	

^aOdds ratios from logistic regression for all binary outcome variables

^bRatios and adjusted mean value for each group from GLM Negative binomial regression analyses

^cRelative risk converted from adjusted odds ratio and percentage of event in each group

^dP-value from logistic regressions or GLM

^eN(%) from unadjusted frequency tables

Abbreviations: CI = confidence interval; LOS = length of stay; min = minutes; N = number of cases; PRBC = Packed Red Blood Cel

PATIENTS AND METHODS - Patient Selection Criteria and Study Groups (paragraph 3)

Current version:

Those patients excluded from the study were those surgery cases with missing baseline study variables and outcomes values. Also major surgeries with surgical times lasting less than 45 minutes or longer than 360 minutes and extreme surgeries lasting less than 90 minutes or longer than 540 minutes were excluded from the study; representing the lower and upper 2% of patients based on surgical time. This exclusion was made to eliminate the impact that observational outliers would have on study results.

Corrected version:

Those patients excluded from the study were those surgery cases with missing baseline study variables and outcomes values. However, if the Floseal size was the only missing value, the patient was kept in the analysis and either a 5 or 10 mL Floseal size was randomly imputed based on the yearly distribution of the 5 mL or 10 mL sizes in the patients in whom the information was available. Also major surgeries with surgical times lasting less than 45 minutes or longer than 360 minutes and extreme surgeries lasting less than 90 minutes or longer than 540 minutes were excluded from the study; representing the lower and upper 2% of patients based on surgical time. This exclusion was made to eliminate the impact that observational outliers would have on study results.

RESULTS

Major Spine Surgery Group - Healthcare Resource Utilization

Current version:

Amount of Hemostatic Matrix Used during Surgery: Surgiflotreated cases were associated with more milliliters of hemostatic matrix product (AD = 3.35 mL, p < 0.0001) compared to Floseal-treated cases. Surgiflo adjusted mean product utilized was 10.99 mL and Floseal adjusted mean product utilized was 7.64 mL.

Corrected version:

Amount of Hemostatic Matrix Used during Surgery: Surgiflotreated cases were associated with more milliliters of hemostatic matrix product (AD = 1.90 mL, p < 0.0001) compared to Floseal-treated cases. Surgiflo adjusted mean product utilized was 10.83 mL and Floseal adjusted mean product utilized was 8.93 mL.

Severe Spine Surgery Group - Healthcare Resource Utilization

Current version:

<u>Amount of Hemostatic Matrix Used during Surgery:</u> Surgiflotreated cases were associated with more hemostatic matrix (AD = 1.52 mL, p < 0.01) compared to Floseal-treated cases. Surgiflo adjusted mean product utilized was 11.71 mL and Floseal adjusted mean product utilized was 10.19 mL.

Corrected version:

<u>Amount of Hemostatic Matrix Used during Surgery</u>: No difference in the volume of hemostatic matrix was found between Surgiflo- and Floseal-treated cases (AD=-0.14 mL, p = 0.8225). Surgiflo adjusted mean product utilized was 11.69 mL and Floseal adjusted mean product utilized was 11.83 mL.