

A comparison of two single-use negative pressure wound therapy devices in the prevention of surgical site complications following Caesarean Section: a real-world evidence analysis

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Background and aims

- Post-operative surgical site complications (SSCs) represent a significant burden to healthcare systems globally and pose many challenges for patients undergoing Caesarean Section (CS)¹⁻²
- The rate of cesarean section (C-section) in the United States (US) increased by 55.1% between 1996 and 2021, from 20.7% to 32.1% of all deliveries^{3,4}
- Surgical site infection (SSI), one of the most common surgical site complications (SSC), has an incidence of 5.3–9.6% in C-section delivery and is associated with increased rates of maternal morbidity and mortality, compared with patients without an SSI^{5,6}
- Wound dehiscence, seroma, and hematoma are also common SSCs in C-sections, with dehiscence of the operative wound representing one of the most common causes of maternal morbidity.
- This study aimed to determine whether the use of a single-use negative pressure wound therapy (sNPWT) system over closed surgical incisions could reduce the incidence of SSCs, the length of hospital stay (LOS), and index admission cost and 30-day costs between two commercially available devices (80mmHg and 125mmHg).

Methods

- A retrospective cohort study was performed using the Premier PINC AI Healthcare Database (PHD), all payor hospital inpatient admissions between 2017 to June 2022.
- Patients who were ≥18 years old and had an inpatient encounter where the –80 mmHg or the –125 mmHg devices were used were identified using a pattern-matching algorithm that searched the billing tables.
- The C-section surgical procedure category was selected based on the Agency for Healthcare Research and Quality Clinical Classifications Software (CCS) tool, which organizes the International Classification of Diseases, Tenth Revision Procedure Coding System (ICD-10-PCS) codes into categories.
- Patients were excluded if they had been treated with both the –80 mmHg and the –125 mmHg device, and if open wounds were present or if an SSC diagnosis was present on admission as identified by ICD-10 Clinical Modification (ICD-10-CM) codes.
- Additional exclusion criteria included multiple surgical encounters where the –80 mmHg device or the –125 mmHg device were used, additional surgery within 30 days, insufficient follow-up, and cases where the cost of the encounter could not be determined.
- To facilitate the comparability, a 1:1 propensity score matching (PSM) was used.
- A greedy matching method where k=1 was implemented using patient characteristics and comorbidities at the index encounter
- Demographic, hospital, and baseline clinical characteristics were used for matching between 80mmHg and 125mmHg cohorts.
- Hypothesis testing, generalized linear and logistic regression models were applied to evaluate differences in costs and clinical outcomes between cohorts.

A retrospective real-world evidence study using the Premier PINC AI Healthcare database demonstrated that the use of an 80mmHg[◊] negative pressure wound therapy device results in a statistically significant reduction in surgical site complications and costs compared to a 125mmHg* negative pressure wound device in patients undergoing cesarean section

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Patient Matching

- After matching, 5332 patients were included for both devices, 5% were smokers, and 0.26% vs 0.58% used steroids, mean age 30, CCI 0.17 and 0.18, see Tables 1a and 1b

Table 1a: Categorical variables

Categorical variable	Level	Unmatched				Matched			
		80 mmHg		125 mmHg		80 mmHg		125 mmHg	
		Number	%	Number	%	Number	%	Number	%
All	All	11,747	100	5,396	100	5,332	100	5,332	100
Gender	Female	11,745	99.98	5,396	100	5,331	99.98	5,332	100
	Unknown	2	0.02	.	.	1	0.02	.	.
Inpatient/Outpatient	Inpatient	11,747	100	5,396	100	5,332	100	5,332	100
Smoker	No	11,225	95.56	5,110	94.7	5,089	95.44	5,061	94.92
	Yes	522	4.44	286	5.3	243	4.56	271	5.08
Steroid use	No	11,678	99.41	5,362	99.37	5,318	99.74	5,301	99.42
	Yes	69	0.59	34	0.63	14	0.26	31	0.58

Table 1b: Continuous variables

Cont. Variable	Level	Unmatched		Matched	
		80 mmHg	125 mmHg	80 mmHg	125 mmHg
All	Number	11,747	5,396	5,332	5,332
Age	Mean	30.12	30.22	29.63	30.19
	Median	30	30	30	30
	Min	18	18	18	18
	Max	50	53	50	53
CCI	Mean	0.16	0.2	0.17	0.18
	Median	0	0	0	0
	Min	0	0	0	0
	Max	7	7	6	6

Table 2: Surgical site complications

Endpoint	Unadjusted						Adjusted		
	Number		Complications		% incidence		Odds ratio 80mmHg: 125mmHg	Odds ratio 80mmHg: 125mmHg	p-val
	80 mmHg	125 mmHg	80 mmHg	125 mmHg	80 mmHg	125 mmHg			
SSI at 30 days	5,332	5,332	31	53	0.58	0.99	0.583	0.584	0.0179
Dehiscence at 30 days	5,332	5,332	55	90	1.03	1.69	0.605	0.616	0.0050
Seroma at 30 days	5,332	5,332	2	9	0.04	0.17	0.235	0.302	0.0500
Hematoma at 30 days	5,332	5,332	8	8	0.15	0.15	1.000	0.980	0.9638
Deep SSI at 90 days	5,178	5,239	1	5	0.02	0.10	0.200	0.285	0.0970

Table 3: LOS and costs at index procedure, 30 days, and 90 days

Endpoint	Unadjusted						Adjusted		
	Number		LOS/Cost (\$)		% reduction (80mmHg vs 125mmHg)		p-value	% reduction (80mmHg vs 125mmHg)	p-val
	80 mmHg	125 mmHg	80 mmHg	125 mmHg	80 mmHg	125 mmHg			
LOS (days)	5,332	5,332	3.39	3.47	2.31%	0.9916	2.35%	0.1009	
Index admission cost (\$)	5,332	5,332	\$10,613	\$11,103	4.41%	0.0009	3.83%	<.0001	
Total cost at 30 days from surgery (\$)	5,332	5,332	\$9,318	\$9,980	6.63%	<.0001	6.12%	<.0001	
Total cost at 90 days from surgery (\$)	5,178	5,239	\$9,472	\$10,200	7.14%	<.0001	6.55%	<.0001	

Results

- Results demonstrate statistically significant reductions in surgical site infections at 30 days, dehiscence, and seroma while showing no difference in hematoma and deep SSIs (Table 2).
- The mean index admission cost, 30-day, and 90-day were significantly lower for 80mmHg vs 125mmHg, and no differences were observed in LOS (Table 3)..

Conclusion

- The prophylaxis use of 80mmHg reduced SSI, dehiscence, and costs compared with 125mmHg in patients undergoing caesarean section.
- No differences were observed for length of stay and the incidence of deep SSI and hematoma.
- The study is bound by the common limitations of administrative discharge data, for example, improper or incomplete coding and missing data.

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