Data Collection: Wound morbidity

- **Checked both perineal and donor site wounds**
- **Wound morbidity included**
  - **Separation**
  - **Infection**
  - **Necrosis**
- **Day of diagnosis of wound morbidity (days after surgery)**
- **Time to wound healing (months)**
- **If an additional definitive reconstructive procedure was required of not**
- **Late hernia**

Data Collection: Costs

- **Costs used had to be able to be reliably identified retrospectively and needed to capture the majority of the clinical costs**
- **Costs chosen were**
  - **Operating time: NZD 40.86 minute**
  - **Hospital stay: Surgical ward NZD 422.33, ICU 5,386.13 day**
  - **District Nurse: NZD 101.69 a visit, VAC dressings approximately NZD 100 a day**
  - **Community costs: Unable to be retrospectively identified**
- **From previous studies it was estimated this would cover up to 75% of the hospital and outpatient costs.**

Results

Comparison of Groups

	RAM	DIRECT	p value
Number of patients	**31**	**38**	
Sex Male:Female	10:21	21:16	**0.043**
Age:Mean (sd)	60.6 (14.2)	56.9 (18.9)	0.506
Pathology			
Adenocarcinoma	12	23	0.0541
SCC	**9**	**1**	**0.0039 (F)**
Other neoplasm	3	1 (FAP – benign)	
IBD (CD: UC)	3 (2:1)	8 (5:2)	0.27
Failed pouch	1	2	
Other	3	2	
Operative details			
Operative time: Median (IQR)	**303 (158)**	**217 (70)**	**<0.001 (MWU)**
No R0 Resection (Cancer)	7 of 24	5 of 24	
Excision other pelvic organs	**7**	**1**	**0.0194 (F)**

Comparison of Groups: Risk factors

- **Significant differences**
  - **RAM group: Significantly more patients had preoperative radiotherapy**
  - **RAM group: Significantly greater number of risk factors (p=0.001)**

- **Non significant associations**
  - **RAM group: More acute cases**
  - **Primary closure: More patients with cardiovascular disease and a history of smoking**

Comparison of Groups

- **Overall the RAM group were higher risk patients with....**
  - **More SCC (larger perineal skin defects)**
  - **More excision of other pelvic organs/more exenterations**
  - **More preoperative radiotherapy**
  - **A greater number of risk factors for wound problems**

- **The ORAM myocutaneous flap added 75 minutes to the operating time**

Number of Wound Complications

- **Any wound complication (p=0.251)**
  - **RAM 21 of 31, 68%**
  - **Primary repair 20 of 37, 54%**

- **Perineal wound complication**
  - **RAM 17 of 31, 55%**
  - **Primary repair 20 of 37, 54%**

- **There were no differences in other complications between the two groups**

Details of Wound Complications

	RAM (31)		Direct (38)	p Value
	Perineal	Abdominal	Perineal	
Minor	11	3	8	
Major	6	4	12	
Time to diagnosis (days)	Median 15 (12.5)		Median 10 (6)	0.012 MWU
Time to healing (months)	**Median 2 (0)**		**Median 5.5 (12.75)**	**0.005 MWU**
Additional definitive operative procedure	**0**		**8**	**0.006 F**
Did not heal at all	1 of 17	1 of 7	3 of 20	

Wound complications and Risk factors

- **There was no association between any individual risk factor (such as RT) and wound complications**
- **There was a non significant association towards patients with <u>>1 risk factor</u> having less wound problems with a RAM flap, p=0.16)**

Length of Stay

- **For the index hospital admission (when the APR was performed)**
  - **Includes prolonged stay because of wound complications**
  - **RAM 13 (12) v Primary closure 13 (8.5), p=0.84 MEDIAN**

- **Additional stay in hospital because of wound complications**
  - **Includes extra days during initial admission and subsequent readmissions to hospital**
  - **RAM 2 (8.5) v Primary closure 7 (28.7), p=0.048 MEDIAN**

Total Costs

	RAM	PRIMARY	Total
Total cost (including costs unrelated to complications and due to complications)			
Operation	456529	495509	952038 (52.5)
Hospital stay	250030	388121	638151 (35.1)
District Nurse	56540	133926	190466 (10.5)
VAC dressing	10678	23343	34021 (1.9)
Total	773777 **(42.7)**	1040899 **(57.3)**	1814676

Total costs between the two groups was similar

Mean and Median Total Costs (Denominator – all patients)

	RAM	DIRECT	p value
Total costs (Costs unrelated to complications and due to complications)			
Mean (sd)	24960 (13037)	28132 (27735)	
Median (IQR)	20948 (11079)	17189 (19958)	**0.298 (MWU)**
Costs when no wound Complications			
Mean (Sd)	18374 (5609)	14884 (4984)	
Median (IQR)	17449 (7669)	14057 (5346)	**0.005 (MWU)**
Costs related to wound complications			
Mean (sd)	6708 (12120)	13306 (27062)	
Median (IQR)	1525 (8819)	406.70 (16417)	0.727 (MWU)

Costs due to complications (Denominator – patients with a complication)

	RAM	DIRECT	p value
Costs due to Perineal wound complications			
Mean (sd)	8394 (15200)	25911 (33466)	
Median (IQR)	2403 (9303)	15611 (30113)	0.012 (MWU)

Complications costing NZD >25,000: ORAM 1 v Direct closure 7, p=0.02 (Fisher)

Summary: Overall results

- **OVERALL Results**
  - **No significant difference in incidence of wound morbidity**
  - **No significant difference in the overall costs**

- **What does this mean?**
  - **There was an appropriate selection in deciding when to perform a direct closure or a RAM flap**
  - **RAM is a good option in high risk patients**

Summary : The perineal wound

- **FREQUECNY OF COMPLICATIONS**
  - **The same for both groups**

- **HEALING OF THE PERINEAL WOUND**
  - **Significant differences in the severity of perineal wound morbidity.**

  For RAM flap patients…
    - **Quicker Healing**
    - **Fewer additional days in hospital**
    - **Fewer definitive reconstructive procedures**

- **COST OF THE PERINEAL WOUND**
  - **For RAM flap patients…**
    - **Perineal wounds significantly less expensive**
    - **Significantly fewer patients in the high cost group of >25,000**

Summary: The perineal wound

- **A vascularised graft may not prevent perineal complications, but it appears that it can enhance the healing of complicated perineal wounds**

Original article

doi:10.1111/codi.13690

A comparison of the cost of primary closure or rectus abdominis myocutaneous flap closure of the perineum after abdominoperineal excision

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Conclusions

1. **Overall no significant difference between the two procedures in appropriately selected cases**
2. **IF you are not going to get a complication then a primary closure is more cost effective**
3. **If you are likely to get a perineal complication then a RAM closure is cost effective**
4. **IF we could avoid primary closure in patients likely to have perineal wound problems this may result in cost savings**
   - **For example, a myocutaneous flap should be the considered in cases where there are three or more risk factors for poor wound healing**

What about using NPWT in closed wounds to help with Perineal Wound Healing?

NPWT in complex open wounds

NPWT has revolutionised the Rx of complex open wounds

NPWT in complex closed wounds

NPWT has had excellent results in case series with closed wounds, such as after major incisional hernia repair...

How does NPWT work?

Protects the incision from external contamination
Hudson *et al*. 2013

Holds closed incision edges together and helps reduce tensile forces across the incision
Leak. 2011
l. 2011 (in vitro)

Reduces seroma a haematoma fluid collections
Pelino *et al*. 2013

ove perfusion
nico *et al*. 2012

a
2

Figure 1: NPWT

Complicated literature

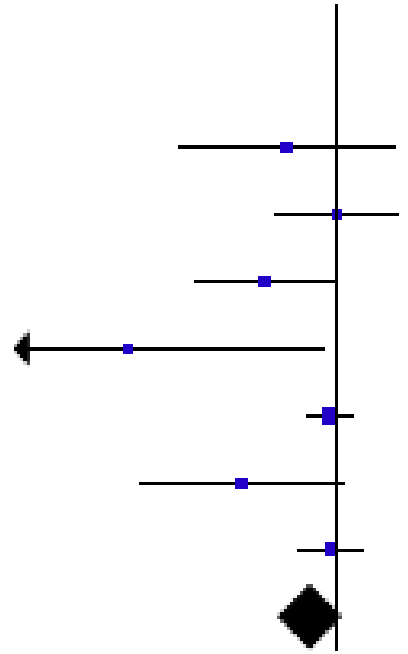
- **Lots of studies**
- **Differences in technique of skin closure**
- **Lots of retrospective case studies and prospective "sequential" studies**
- **RCTs often (but not always) poorly blinded**
- **Studies with conflicting results**
- **The differences in outcomes is less in higher quality studies than in all studies**

Cochrane Review: NPWT for surgical wound healing by primary closure

- **2020 update**
- **44 RCTs in 7447 patients comparing NPWT with standard care, for a variety of procedures**
- **39 RCTs assessed SSI (6208 patients), showing a reduction from 13% with standard dressings to 8.8% with NPWT, RR 0. 66 (0.55-0.80)**
- **High quality studies, including assessor blinding – 6 studies, 2229 patients, 10.4% v 13.5% SSI, RR 0.75 (0.56-1.00)**
- **No differences in seroma, haematoma, dehiscence**
- **Concern about high risk of bias in approximately half the RCTs**

Cochrane Review: “General abdominal”

1.2.6 General: abdominal						
Bobkiewicz 2018	2	15	4	15	1.3%	0.50 [0.11 , 2.33]
Kuncewitch 2017	8	36	8	37	3.6%	1.03 [0.43 , 2.44]
Leon 2016	5	47	10	34	3.0%	0.36 [0.14 , 0.96]
Lozano-Balderas 2017	0	25	10	27	0.4%	0.05 [0.00 , 0.83]
Murphy 2019	46	144	48	140	11.0%	0.93 [0.67 , 1.30]
O'Leary 2017	2	24	8	25	1.5%	0.26 [0.06 , 1.10]
Shen 2017	26	132	28	133	8.0%	0.94 [0.58 , 1.51]
Subtotal (95% CI)		**423**		**411**	**28.8%**	**0.69 [0.45 , 1.06]**



Non significant difference in favour of NPWT [21% v 28% RR Ratio 0.69 (0.45-1.06)]

Largest studies, with >100 patients have the smallest difference

A larger study with uncertain blinding.....

NPWT after Caesarean section

- **Published 2018, Denmark (Hyldig)**
- **Obese women (BMI>30) undergoing elective of acute CS**
- **NPWT using PICO for 5 days**
- **Skin closure by surgeon preference**
- **Primary outcome SSI requiring antibiotics within 30 days**
- **National health data registries used, but no evidence initial assessment for diagnosis and treatment was blinded**

NPWT after Caesarean section

- **SSI in 20 of 4332 in (4.6%) NPWT and 41 of 444 (9.2%) controls, p=0.007**
- **Matches our LUCS "experience" in Dunedin (when NPWT was introduced for high risk patients the number of cases presenting to the wound clinic reduced)**

Larger study with good blinding.....

NEPTUNE Study

(NEgative Pressure wound Therapy Use to decrease Nosocomial Events)

- **Published 2019, Canada (Murphy)**
- **Open elective colorectal surgery (includes conversion form laparoscopic).**
- **Excluded APR, exenteration and acute surgery.**
- **No details on skin closure**
- **NPWT (-125mmHg first 5 days) v gauze dressing**
- **RCT, assessor blinded**
- **Randomised 300, 284 in final assessment**
- **Primary endpoint 30 day SSI**

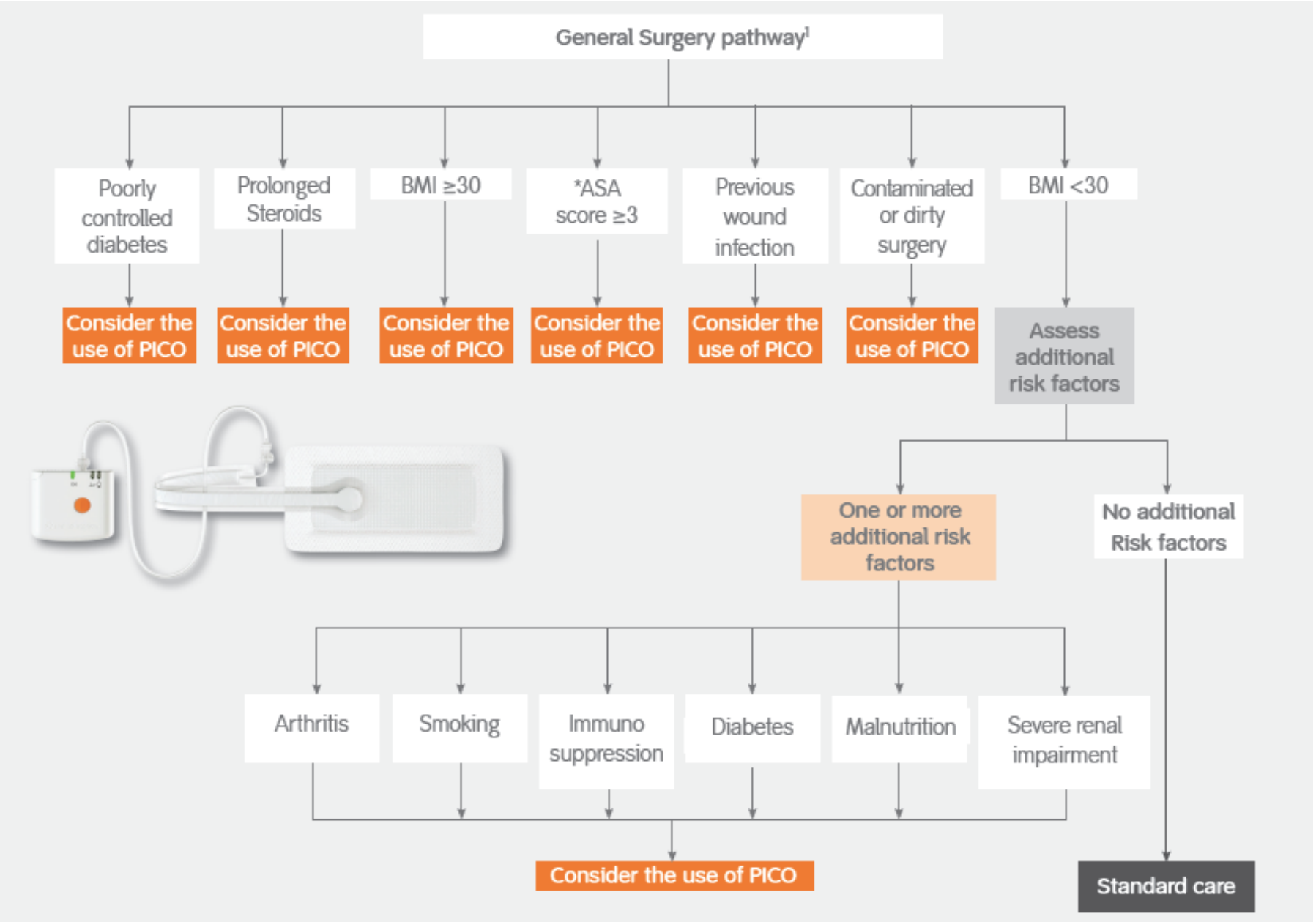
NEPTUNE Study

- **Randomised 300 patients**
- **Groups well matched**
- **No difference in SSI: 32% NPWT v 34% control**
- **No difference in SSI with stoma: 38% NPWT v 33% control**
- **No difference in LOS: mean 7 days, IQR 5 both groups**
- **NO differences in other complications between groups**
- **Not assessing ‘high risk’ patients in terms of acute surgery and contamination, but high risk in terms of baseline SSI (>30%) and ASA (>75% were ASA III/IV)**

NEPTUNE Study

- **No benefit for NPWT in elective open abdominal colorectal surgery**

What about in high risk wounds?



Maybe NPWT will have better results in high risk wounds

The data has the same challenges as studies looking at all cases

NPWT and the perineal wound…..

NPWT and the Perineal wounds

- **Difficulty getting a seal**
- **Potential issues with volume of drainage**
- **No RCT data**
- **Conflicting results in pilot studies**
- **The perineal wound = a high risk wound**

Perineal wounds – Pilot study

- **Van der Valk, Netherlands, 2017**
- **Pilot study with 10 patients in each group**
- **Two consecutive groups, 10 patients in each group**
- **Laparoscopic APR with biological mesh placement in pelvic floor. Suture closure, using a variety of techniques**
- **PICO -80mmHg for 7 days**
- **PICO: 2 problems with sealing**
- **7 wound problems in 10 PICO patients, 6 in 10 controls**

Perineal wounds – Pilot study 2

- **Sumrien, Bristol UK, Tech Coloproct 2016**
- ***"Consecutive groups" with multiple changes***
- **Changes included: From Traditional APR, in lithotomy, occasional use of biological mesh to ELAPE, prone, routine pelvic floor biological mesh, NPWT**
- **NPWT 125mmHg for a median of 5 days. Deep subcutaneous drain, subcuticular skin closure**
- **Historical group 10/25 major wound problems v Prospective group 1/32 1 major and 2 minor wound problems**

Perineal wounds – Study 3

- **Chadi et al, Canada, DCR 2014**
- ***Consecutive groups, no blinding***
- **Single surgeon, all patients having APR over 4 years.**
- **Interrupted sutures to skin, no comment on drains**
- **VAC based NPWT, 125mmHg for 5 days**
- **No assessor blinding (surgeon the main assessor)**
- **Historical group 13/32 SSI (41%) and NPWT group 4/27 (15%), p=0.04**
- **LOS the same as most SSI developed after discharge**

It is unclear if NPWT over a closed Perineal wound will make a difference to rates of wound complications

NPWT: Is there a ‘double ring’ moment?

- **Would a subcutaneous perineal drain attached to a NPWT canister have advantages over a normal drain?**

Some Conclusions about SSI in colorectal surgery

- **A major pelvic floor excision is associated with many challenges managing the perineal wound**
- **If a perineal wound breaks down, if will often take six months to get healed and may need a further surgical procedure**
- **For a small skin defect with few risk factors simple closure is best**
- **For a large defect, or when there are multiple risk factors, a myocutaneous flap is a good option**
- **At this stage there is minimal high quality evidence that NPWT placed over the closed perineal wound will prevent problems.**