38th Annual Congress of Korean Association of HBP Surgery (KAHBPS)
April 26-27, 2013 in Jeju Island

Session Title: Enhanced Recovery After Surgery (ERAS) in HBP field

Evidence-based management of surgical drain after pancreatectomy

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Fast-Track Surgery (Clinical Pathway)

Pre-op assessment/ optimization

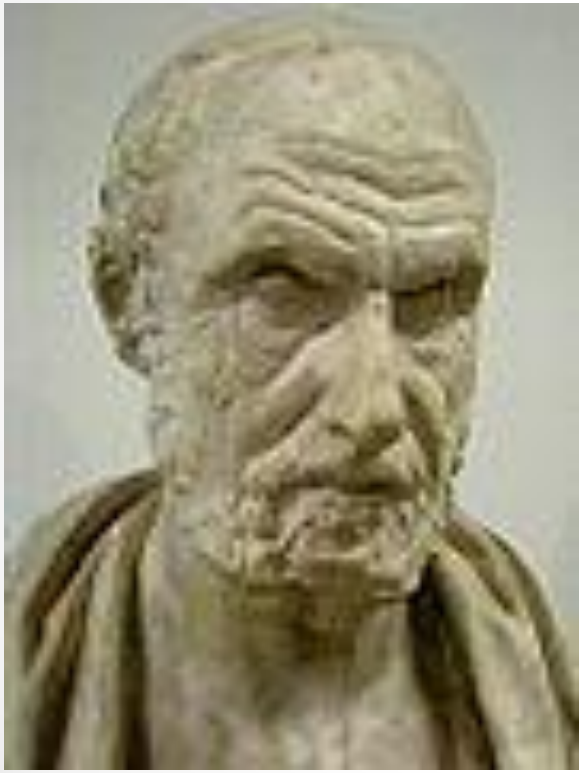
- patient information
- stress reduction
- pain relief
- additional interventions
- revision of care principles (drains etc.)
- oral nutrition
- ambulation, exercise

enhanced recovery

Today's Contents

- History of Drains and Drainage Procedures
- Clinical Evidence of Drain Management for Pancreatectomy
- Emerging Strategy of Drain Management: No Drain Policy

History of Drains and Drainage Procedures



Hippocrates (460 to 377 BC)

The first physician described the use of hollow tube for surgical drainage to treat empyema

Before Century

History of Drains and Drainage Procedures

Ambroise Paré (1510-1590):
Barber and Military surgeon

The first surgeon cautioned against the excessive use of drains and described the complications and drawbacks of the drains

Management of therapeutic drains

The Middle Age

History of Drains and Drainage Procedures

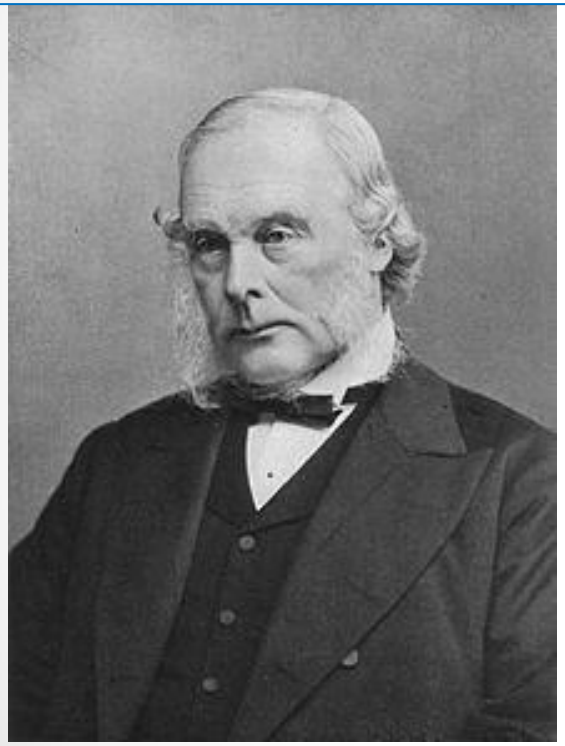
The first surgeon introduced prophylactic drainage of the peritoneal cavity after GI surgery.

The Modern Age

Albert Theodor Billroth(1829-1894):

History of Drains and Drainage Procedures

"The Father of modern antisepsis"



Joseph Lister (1827-1912): Professor of Univ of Glasgow, Edinburgh, and King's college

The first surgeon developed antiseptic technique for wounds

importance of constant cleaning of the tubes and prevention of infection .

The Modern Age

History of Drains and Drainage Procedures

Lawson Tait (1845–1899)
Birmingham Womens Hp
University of Birmingham

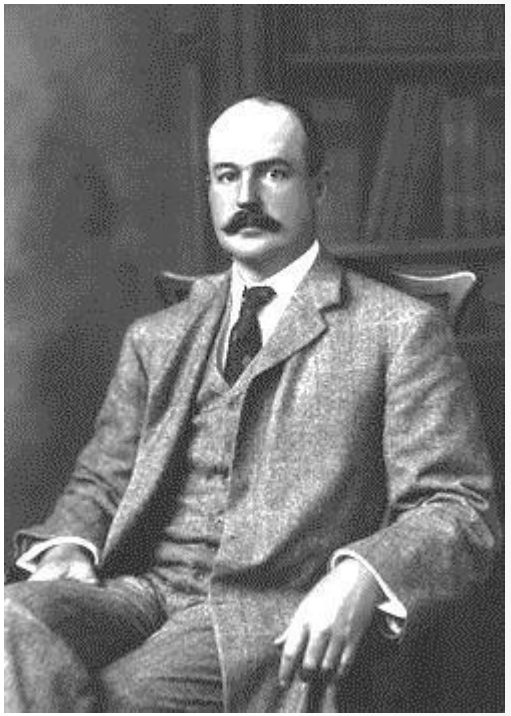
"When in doubt, Drain!!!"

The Modern Age

Drain placement has been common in the field of GI surgery

History of Drains and Drainage Procedures

The first surgeon introduced the new type of drain which was made by the cutting the end of a condom and placing gauze inside of it, to eliminate difficulty of drain removal.



Penrose,Charles Bingham(1862–1925)
Professor of Gynecology,
University of Pennsylvania

History of Drains and Drainage Procedures

Drain-related complications at alarming rates.

<Different types of drains>

- Cigarette drains
- Siphon and sump drains
- Cellophane drains
- Suction drainage system

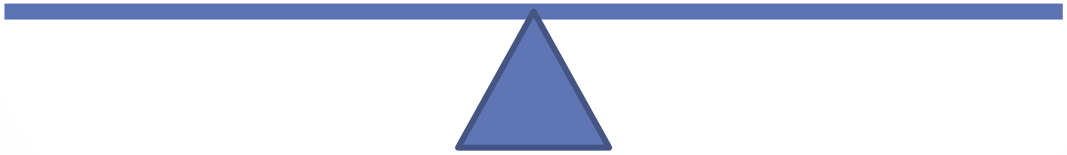
The early 20th century

"When in doubt, Do not Drain!!!"
Because of drain-related complications

Benefit and deficit of prophylactic drain

Benefits
- Drainage of intra-peritoneal fluid collection
- Information of bleeding and leakage

Deficits (as a foreign body)
- Drain tract infection (ascending infection)
- Hemorrahge
- Fistula
- Perforation
- Adhesion
- Incisional hernia
- migration



A use of prophylactic drain is still controversial.
Levy M. Am J Surg. 1984;147:309-314.

History of Drains and Drainage Procedures

The late 20th century

No Drain Policy for Most GI surgeries

Appendicectomy, Cholecystectomy, Hepatectomy, Colectomy, and Gastrectomy

Prophylactic drainage is useless in preventing complications and is even harmful by increasing the risk of intra-abdominal infection.

General Principles for a use of drain: pancreatectomy

The First pancreatectomy by Kausch in 1912 by Whipple in 1935

With routine drain use

High Mortality

High Morbidity

The 20th century

"When in doubt, Do Drain for pancreatectomy!!!"

Levy M. Am J Surg. 1984;147:309-314.

Breakthrough for drain management after pancreatectomy by Wakayama group

	Late removal (POD8, n=52)	Early removal (POD4, n=52)	P value
POPF	12 (23%)	2 (3.8%)	0.038
Intra-abd. infection	20 (38%)	4 (7.6%)	0.0003
	POD 7	POD 4	
Drain culture (+)	31%	4%	<0.05

Kawai and Yamaue et al. *Ann Surg* 2006;244: 1–7

KMU experiences; Introduction of departmental policy (DP)

Deparmental policy (DP) since 2004
(1) duct-to-mucosa pancreaticojejunostomy (2) early removal of closed-suction drain within POD-6
(3) Clinical pathway

	Before DP (n=77)	After DP(n=51)	P value
PJ	Invagination	Duct-to-mucosa	
Drain	Open (penrose)	Closed suction	
Criteria of drain removal	None	Done	
Clinical pathway	None	Done	
Day of drain removal (<POD 6)	1%	53%	<0.0001
Overall complications	64%	39%	0.011
Grade B/C POPF	19%	6%	0.038
DGE	23%	6%	0.013
Duration of in-Hp stay	41(18-132)	24(11-73)	<0.0001

Satoi S et al. Pancreas 2008;37:128-133.

Drain management according to patients at risk for (clinically relevant) POPF

- Risk factor for Overall POPF in 137 patients (PD or DP)

: the amylase value in drains in POD1 ≥5000 U/L (NPV 98%)

Molinari et al. *Ann Surg* 2007;246: 281–287

- Risk factor for POPF (grade B/C) in 1239 patients (PD)

: POD 1 ≥ 4,000 IU/L (PPV 51% for POPF B/C)

Kawai et al. (project study group) J Hepatobiliary Pancreat Sci (2011) 18:601–608

Pancreatectomy

Pts at low risk for POPF (drain-AMY: POD1<5000)

Pts at high risk for POPF (drain-AMY: POD1 ≥ 5000 or 4000)

Early Versus Late Drain Removal After Standard Pancreatic Resections

Results of a Prospective Randomized Trial from Verona group

A total of 114 eligible patients at low risk of POPF according to amylase value in drains 5000 U/L on POD 1

	Late removal (POD5, n=57)	Early removal (POD3, n=57)	P value
POPF	15 (26%)	1 (1.8%)	0.0004
Abd.comp	30 (53%)	7 (12%)	0.001
Pulmonary comp	30 (53%)	15 (26%)	0.007
Any comp	35 (61%)	22 (39%)	0.024
In-Hp stay	10.8±6.9	8.7±4.0	0.048
total cost (Euros)	12,140 (6400)	10,071 (2700)	0.020

Bassi et al. *Ann Surg* 2010; 252: 207–214

The 21st century

The time has come for pancreatic surgeons to accept that long-term drainage is not beneficial and is probably harmful.

Drains should be routinely placed or not following pancreatectomy ?

No Drain vs. Drain in Pancreatectomy

Institution	Study design	Group	Mortality	Overall comp	Readmission	Re-intervetion
MSKCC 2001	RCT (PD+DP)	No drain (n=91)	2%	57%	11%	8%
		Drain (n=88)	2%	63%	22%	13%
Houston 2011	Cohort (PD+DP)	No drain (n=47)	1%	47%* (PF/DGE/ w.infect)	17%	11%
		Drain (n=179)	1%	65%	9%*	2%*

*p<0.05

No Drain vs. Drain in Pancreatectomy

Institution	Study design	Group	Mortality	Overall comp	Readmission	Re-intervention
France 2013	Matched control	No drain (n=27)	3.7%	56% (PF 0%*)	3.7%	3.7%
		Drain (n=27)	3.7%	70% (PF 22%)	0%	3.7%
MSKCC 2013	Surgeon's choice	No drain (n=353)	3%	G3/4 30% PF 17%*	21%*	14%
	(PD)	Drain (n=386)	1%*	36% 27%	28%	18%
Emory 2013	Surgeon's choice	No drain (n=458)	30days 2.5%	54%*	16.8%	6.3%
	(PD)	Drain (n=251)	2.0%	68%	17.5%	8.4%

*p<0.05

Limitations of articles on no drain policy

- Retrospective analysis except one RCT from MSKCC
- RCT did not show the rejection of the hypothesis
- No description of the date of drain removal in Drain group
- Standard pancreatectomy but not extended pancreatectomy (following neoadjuvant therapy)

Clinical efficacy of No drain policy still remains controversial.

On going RCT

Fisher WE.

Randomized prospective multicenter trial of pancreas resection with and without routine intraperitoneal drainage.

PE; 60days morbidity

SE; severity of complications, frequency of specific complications, 90 days mortality

Enrollment; 825 pts

Enrollment is temporarily suspended while an interim data analysis is being performed.

ClinicalTrial.gov. NCT01441492

Summary

In summary, we, pancreatic surgeons, should accept that long-term drainage after pancreatectomy is not beneficial and is probably harmful. The clinical efficacy of the no-drain policy should be investigated in a randomized fashion.

We must never forget that drains cannot compensate for poor surgical judgments and techniques.

Many Thanks for your kind attention

Come, See and Enjoy discussing with us for our future!!!

Kansai Medical University and Hospital

The New University Building was completed on 1st April 2013 !!!

Drains should be routinely placed or not following pancreatectomy ?

drainage after appendicectomy, cholecystectomy, hepatectomy, colectomy, and gastrectomy is useless in preventing complications and is even harmful by increasing the risk of intra-abdominal infection.

Critics have argued that these studies cannot be applied to hepatobiliary and pancreatic surgery because the potential ramification of an undrained collection could be devastating to the patient.

The RCT from New York group in 2001 and observational studies from Houston group in 2011 or New York group in 2013 demonstrated that routine prophylactic drainage after pancreatic resection could be safely abandoned. Recently, French group assessed in a matched control study whether abdominal drainage could be omitted after PD in patients at low risk of PF. The results showed that the PF rate and hospital stay were significantly reduced in the no drainage group relative to the drainage group. They concluded that abdominal drainage should not be considered routinely after PD in patients at low risk of PF.

A Randomized Prospective Multicenter Trial of Pancreas Resection With and Without Routine Intraperitoneal Drainage [Internet]. In: ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US) [cited 2012 Nov 2]. Available at, http://www.clinicaltrials.gov/ct2/show/NCT01441492; 2011. NLM Identifier: NCT01441492. Accessed January 13, 2013.

Discussion

NCT01441492
2011 Sep 23-2013 Dec
A randomized prospective multicenter trial of pancreas resection with and without routine intraperitoneal drainage
PE; frequency of complications within 60days of surgery.
SE; severity of comlications (60days), frequency of specific complications, 90 days mortality
Enrollment; 825 pts
WE Fisher, Bayler College of Medicine, Houston, TX, USA

Enrollment is temporarily suspended while an interim data analysis is being performed.

Houston conclusion: bandoning the practice of routine intraperitoneal drainage after
a pancreatic resection may not increase the overall incidence or severity of severe post-operative complications but the spectrum of complications may be altered. The benefits derived by patients who avoid drains may be offset by a subset of patients who require readmission and post-operative percutaneous drainage.
Conflicts of

A no-drain policy after pancreatectomy may be safe by permitting low rates of re-intervention, re-operation and readmission.
As a realistic policy, a prospective randomized clinical trial is needed to investigate the clinical efficacy of no drainage after pancreatectomy in patients at low risk of PF.

Summary

In summary, we, pancreatic surgeons, should accept that long-term drainage after pancreatectomy is not beneficial and is probably harmful. The clinical efficacy of the no-drain policy should be investigated in a randomized fashion.

Drain management according to patients at risk for (clinically relevant) POPF

Pancreatectomy

In patients at low risk of pancreatic fistula, intra-abdominal drains can be safely removed on POD 3 after standard pancreatic resections.

A prolonged period of drain insertion is associated with a higher rate of postoperative complications with increased hospital stay and costs.

Pts at low risk for POPF
(drain AMY POD1 <500)

Risk factor for Overall POPF in 137 patients who underwent PD or DP
: the amylase value in drains in POD1 ≥5000 U/L (NPV 98%)
Molinari et al. *Ann Surg* 2007;246: 281–287

Risk factor for clinically relevant POPF (grade B/C) in 1239 patients who underwent PD
: POD 1 ≥ 4,000 IU/L (PPV 51% for POPF B/C)
Kawai et al. (project study group) J Hepatobiliary Pancreat Sci (2011) 18:601–608

In conclusion, the present study indicates how it is possible to identify the risk of PF formation on POD1 by analysis of amylase levels in drains. This possibility opens new frontiers in postoperative management. In fact, it is possible to identify a subgroup of patients at high risk for developing complications (POD1 amylase levels 5000 U/L) in which the patient may benefit from lengthening the time of intensive postoperative therapy including prolonged fasting and "in situ" drainage (Table 6). On the other hand, those patients not at risk (NPV 98% on all the pancreatic resection procedures) may be candidates for earlier removal of drains, thus avoiding infections, bedsore lesions, and favoring faster realimentation and discharge from the hospital.29

Demerit of Drain
In the absence of physiological data, it is difficult to argue
that drainage catheters cause pancreatic fistula; however, their routine
use may have negative effects.
Additionally, multiple reports and
prospective trials have suggested that percutaneous drains may create
a pathway for retrograde infection,2,8,22,23 and as was found in the
present article, they have been shown to be associated with development
of intraabdominal infectious complications.

Merit of Drain
we were taught that the
theoretical (never proven) advantage of drainage was to identify an early bile, pancreatic
or enteric leak, or postoperative hemorrhage and thereby treat earlier by reoperation,
transfusion, or modern interventional treatment; or in some cases, the drain would control
the leak and remove the need for intervention.

Operative Drainage Following Pancreatic Resection

Analysis of 1122 Patients Resected Over 5 Years at a Single Institution

Re-admission rate
N=1122 Memorial-sloan kettering center
20% vs27%
Readmission occurred in 23% of patients and postoperative interventions were required in 18% (5 reoperations and 192 interventional radiology-guided drainages). Overall and grade ≥3 morbidities were more commonly seen in patients who had operative drains placed (54% and 33% vs 48% and 26%, respectively; both $P < 0.05$).
No NAC(RT)

The management of operative drains has been the subject of many recent reports.11,19–21 The Verona group has recently published a well-designed trial comparing early (postoperative day 3) versus late (postoperative day 5 or later) drain removal, concluding that early drain removal in patients at low risk for fistula was safe. Prolonged drainage was associated with higher postoperative complication rates and prolonged hospital stays.

it does provide very valuable data
underscoring the potential negative effects derived from the routine and prolonged use of operative drains.

Conclusion.
The results of this study suggest that routine drainage of the operative bed is not associated with improved outcomes. Patients who had operative drains placed did not experience decreased rates of pancreatic fistula, and when pancreatic fistulae occurred, the placement of drains at the initial operation was not associated with decreased postoperative procedures, readmission rates, reoperative rates, overall morbidity, or mortality. Current level I and level II evidence does not support routine drainage of the operative bed following pancreatectomy and suggests that operative drainage may be associated with higher rates of infectious complications.

In a recently published study, Fisher et al report results from a prospective cohort of 47 consecutive patients undergoing pancreatic resection without operative drainage and compared their outcomes with a historical cohort of 179 consecutive patients.8 They found that patients who had prophylactic operative drains placed had higher overall complication rates and complication severity scores. Clinically significant fistula rates were similar between the 2 groups; however, patients without operatively placed drains had higher readmission
and interventional radiology procedure rates. Mortality and reoperation rates were equivalent.

Introduction

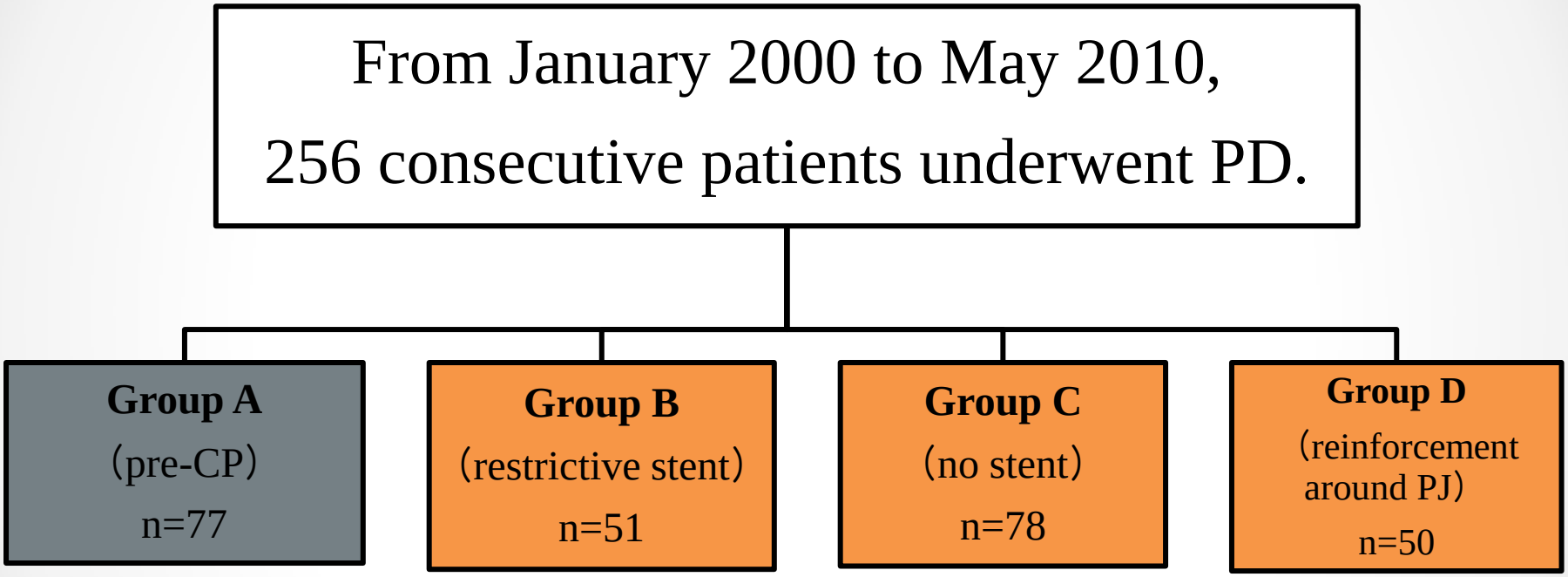
- Pancreaticoduodenectomy (PD) is associated with high morbidity and mortality still in the high volume center.
- Introduction of clinical pathways provide a standardized care plan with identifiable outcomes for patient care.
- There is little data to support the clinical pathway use in this procedure.

Objective

- In June 2004, the new departmental guidelines for peri-operative management of PD were introduced, and a clinical pathway (CP) for all patients undergoing PD was implemented for checking clinical outcomes.

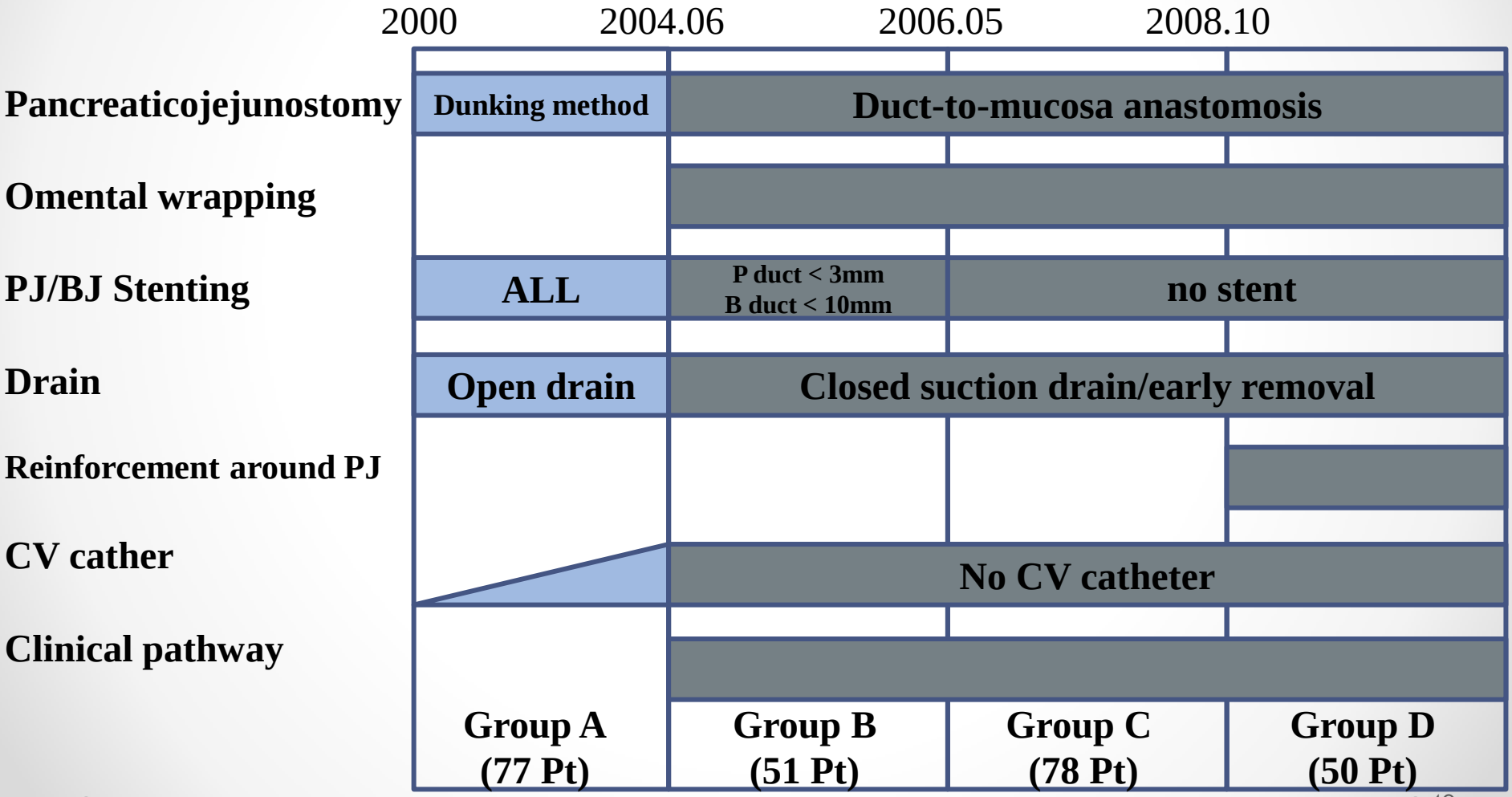
- The objective of this study is to determine
  the clinical effects of clinical pathway implementation.

Patients and Methods



Clinical outcome data, post-operative mortality and morbidity between each group were analyzed.

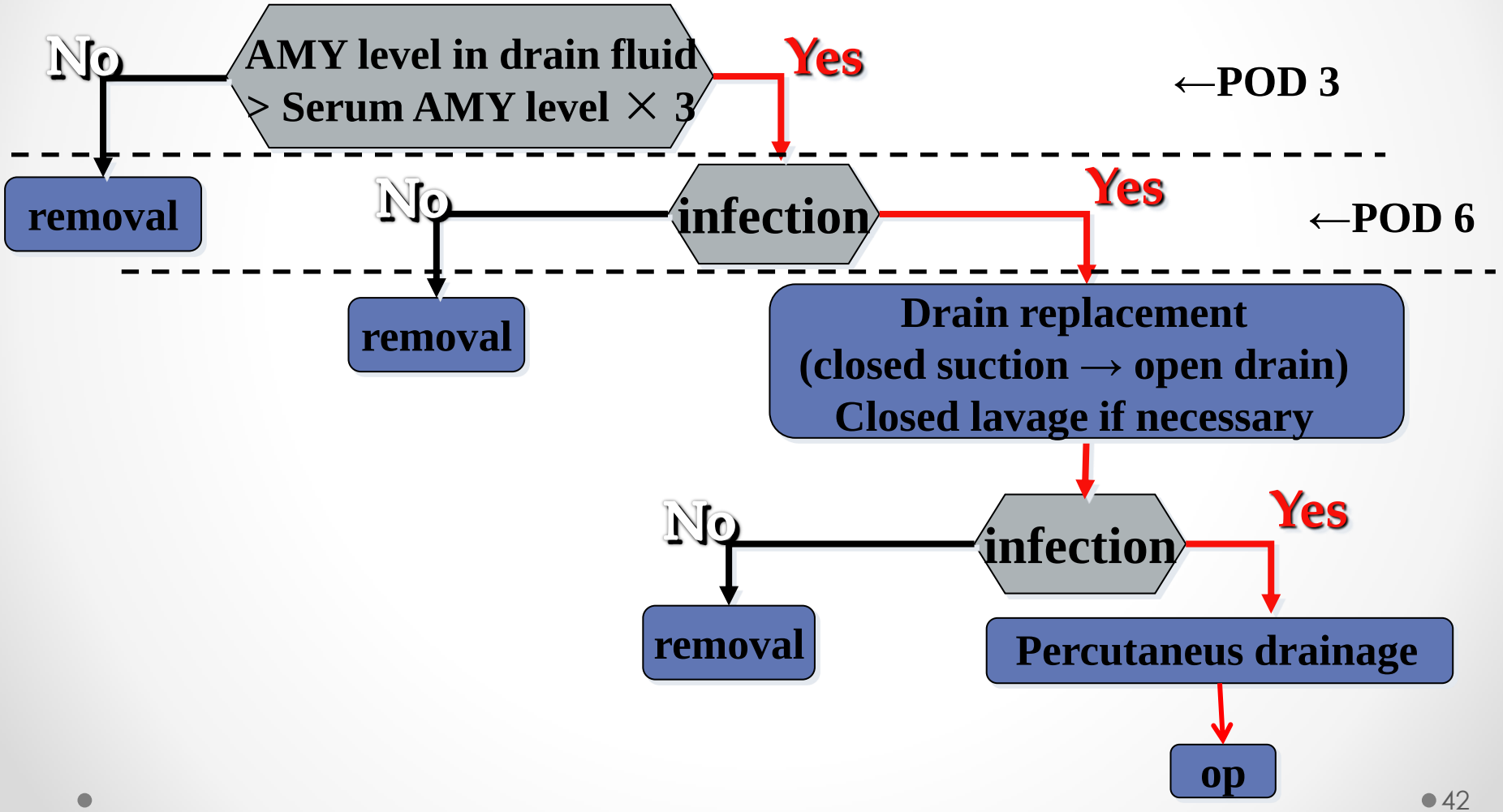
Transition of peri-operative management



Clinical outcomes

Parameter	expected day on CP outline
N/G tube removal	POD 1
Discontinuation of antibiotics	POD 2
Drain removal	< POD 6
initiation oral intake	< POD 7
Discharge from hospital	< POD 21

Criteria of drain removal



Results

Patients' characteristics and intra-operative parameters

parameter	Group A	Group B	Group C	Group D	*p*
age	65(47-843)	68(51-84)	66(36-90)	66(33-82)	n.s.
Male/Female	43/35	33/18	51/27	31/19	n.s.
Panc/Bile/Vater	42/20/15	29/9/13	46/13/19	27/6/17	n.s.
Benign/Malignamt	4/73	4/47	13/65	7/43	n.s.
PD/PpPD	53/24	33/18	42/36	22/28	n.s.
Operation time(min)	545 (300-905)	523 (355-795)	468* (275-714)	440 (327-711)	*0.0086
Blood loss(ml)	1170 (375-7250)	1140 (212-6420)	952 (272-5238)	884 (110-3853)	n.s.

* v.s. group B

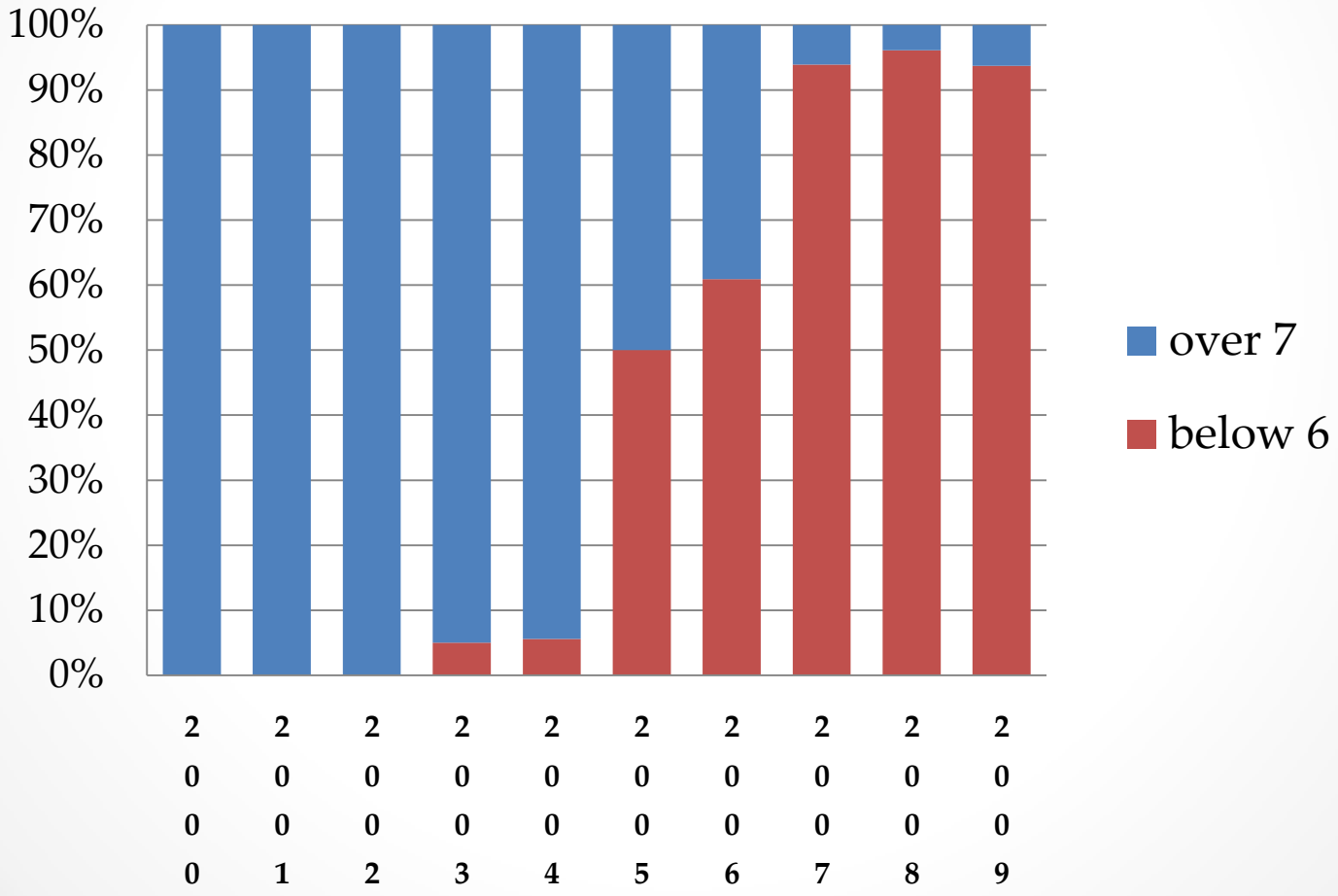
Success rate of clinical outcomes

outcome	Group A	Group B	Group C	Group D	*p*
N/G tube removal ≤ POD1	11(14.3%)	35(67.3%)*	72(92.3%)**	47(94.0%)	* <0.0001 **0.0010
Prophylactic antibiotics ≤ POD2	17(22.1%)	42(80.8%)*	78(100%)**	47(94.0%)	* <0.0001 **<0.0001
Drain removal ≤POD6	1(1.3%)	24(46.2%)*	73(92.3%)**	47(94.0%)	* <0.0001 **<0.0001
Start oral intake ≤ POD7	11(14.3%)	35(67.3%)*	77(97.4%)**	48(96.0%)	* <0.0001 **<0.0001
Patient discharge ≤ POD14	0(0%)	7(13.5%)*	49(62.8%)**	29(58.0%)	* 0.0013 **<0.0001

Post-operative complications

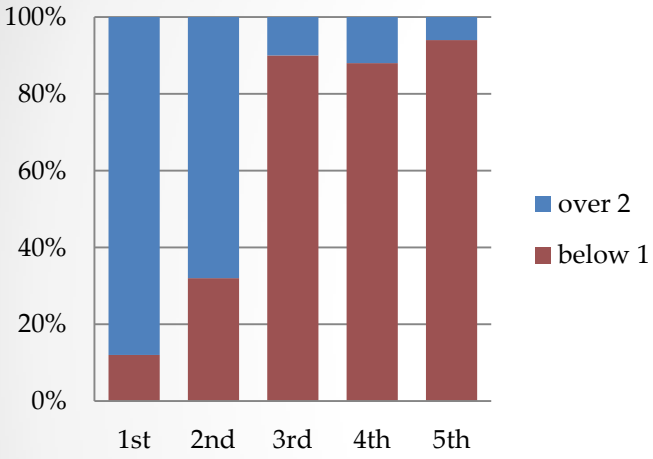
parameter	Group A	Group B	Group C	Group D	*p*
Overall complication	49(64%)	20(39%)*	40(51%)	30(60%)	* 0.0109
DGE	17(23%)	3(6%)*	6(8%)	7(14%)	*0.0133
POPF	21(27%)	7(14%)	34(44%)**	17(34%)	** 0.0004
Grade B/C	15(19%)	3(5.9%)*	11(14%)	5(10%)	* 0.0376
Wound dehiscence	22(29%)	10(20%)	12(15%)	9(18%)	n.s.
Abdominal abscess	7(9.1%)	2(3.9%)	6(8%)	3(6%)	n.s.
Bleeding	1(1.3%)	0(0%)	0(0%)	0(0%)	n.s.
Re-admission	2(2.8%)	0(0%)	2(2.5%)	0(0%)	n.s.
Hospital death	0(0%)	1(2.0%)	3(3.8%)	1(2%)	n.s.

KMU experiences;
Outcome measures in clinical pathway
Success rate of drain removal on POD-6 since 2004

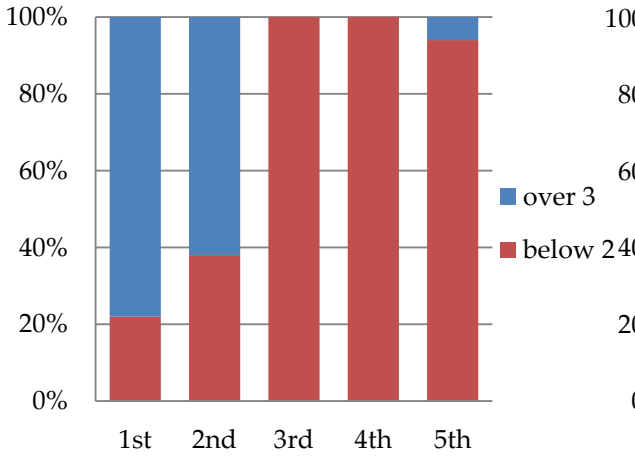


Success rate (every 50 patients)

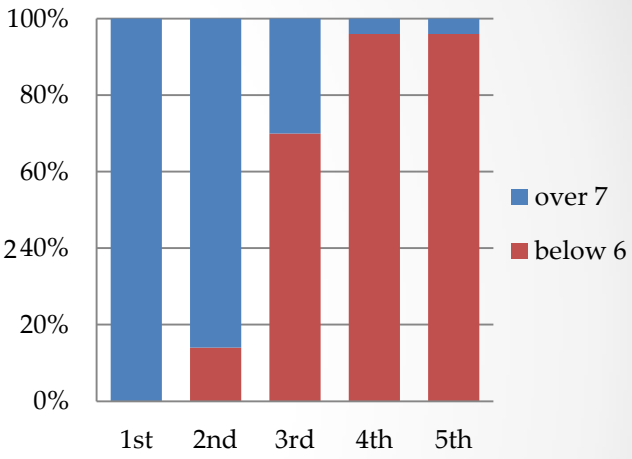
N/G tube removal



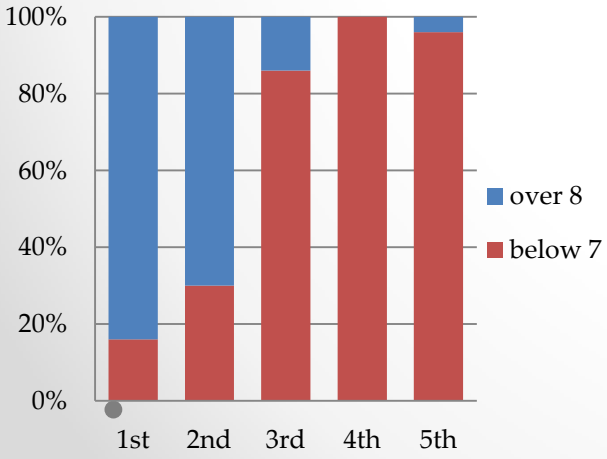
Prophylactic anti-microbial agent



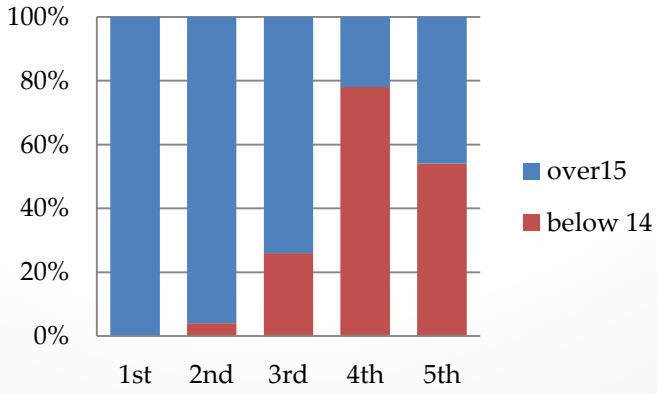
Drain removal



Oral intake



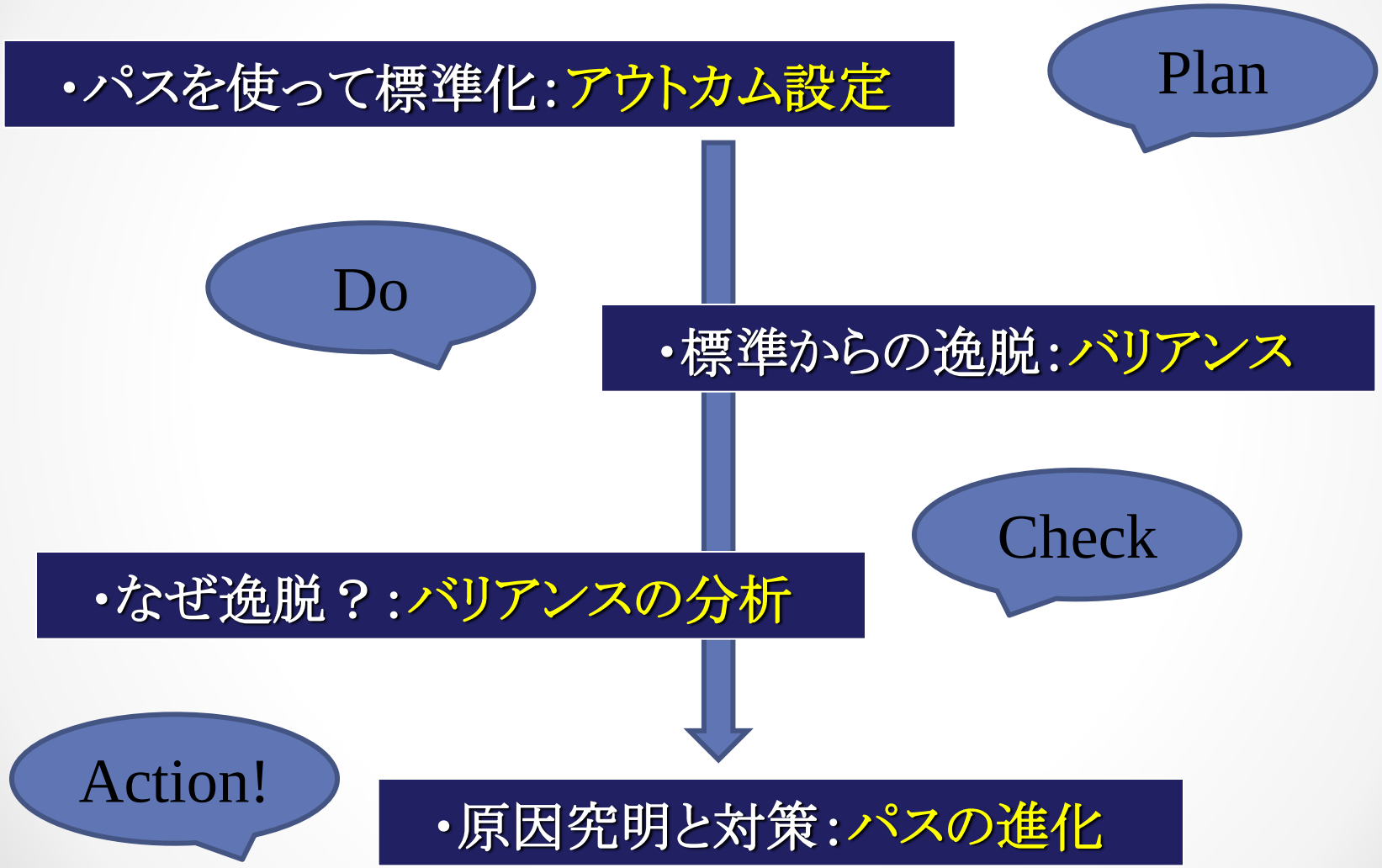
Patient discharge from Hp



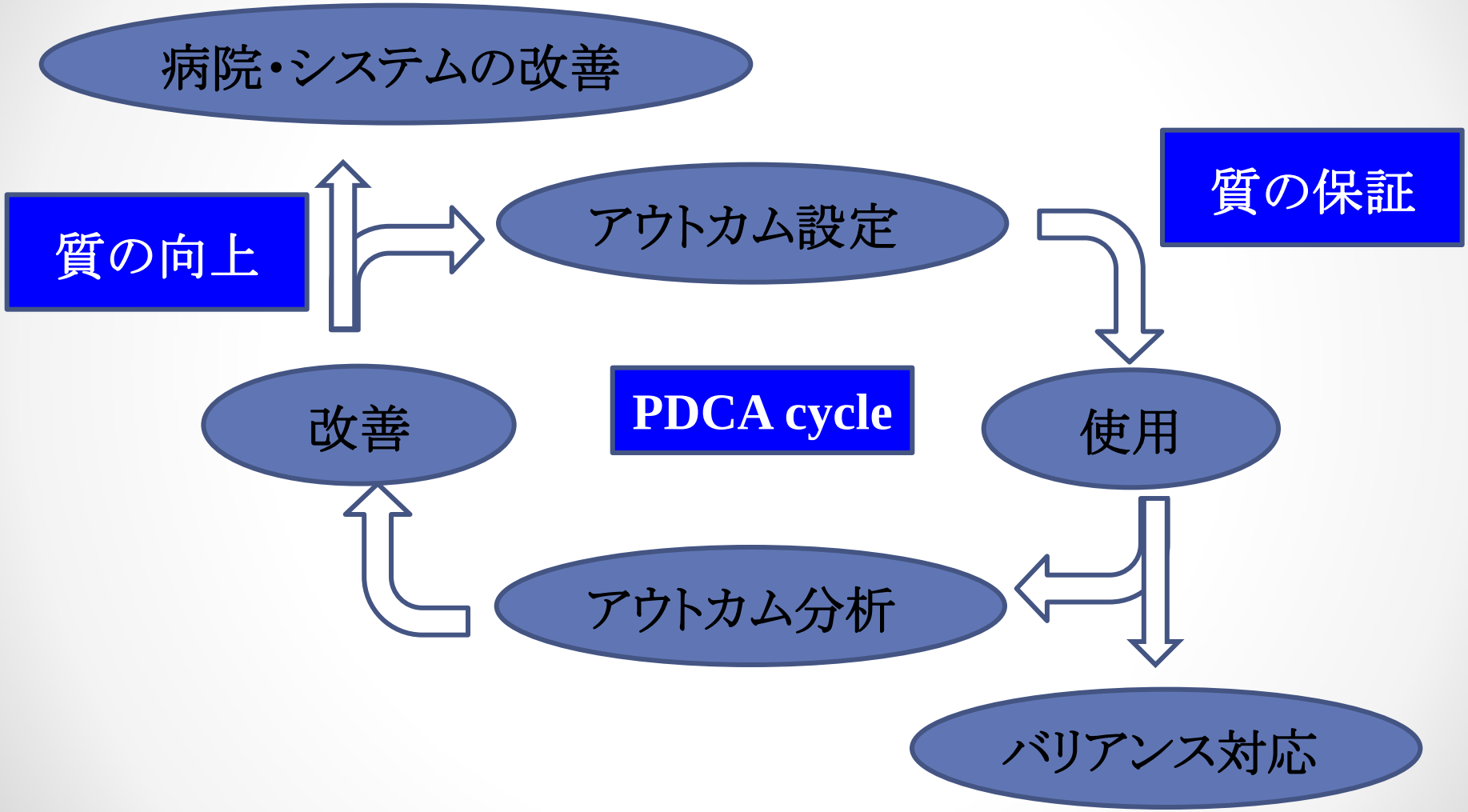
Conclusion

- Long term use of a critical pathway is associated with improved clinical outcomes.
- A certain period of time, or volume of patients is needed for this improved rate of clinical outcomes to reach a plateau, which indicated achieving standardization of peri-operative management.

クリニカルパスの進化


•パスを使って標準化：アウトカム設定
Plan
Do
•標準からの逸脱：バリアンス
Check
•なぜ逸脱？：バリアンスの分析
Action!
•原因究明と対策：パスの進化

バリアンス分析の価値


病院・システムの改善
質の向上
アウトカム設定
質の保証
改善
PDCA cycle
使用
アウトカム分析
バリアンス対応
個別性の重視

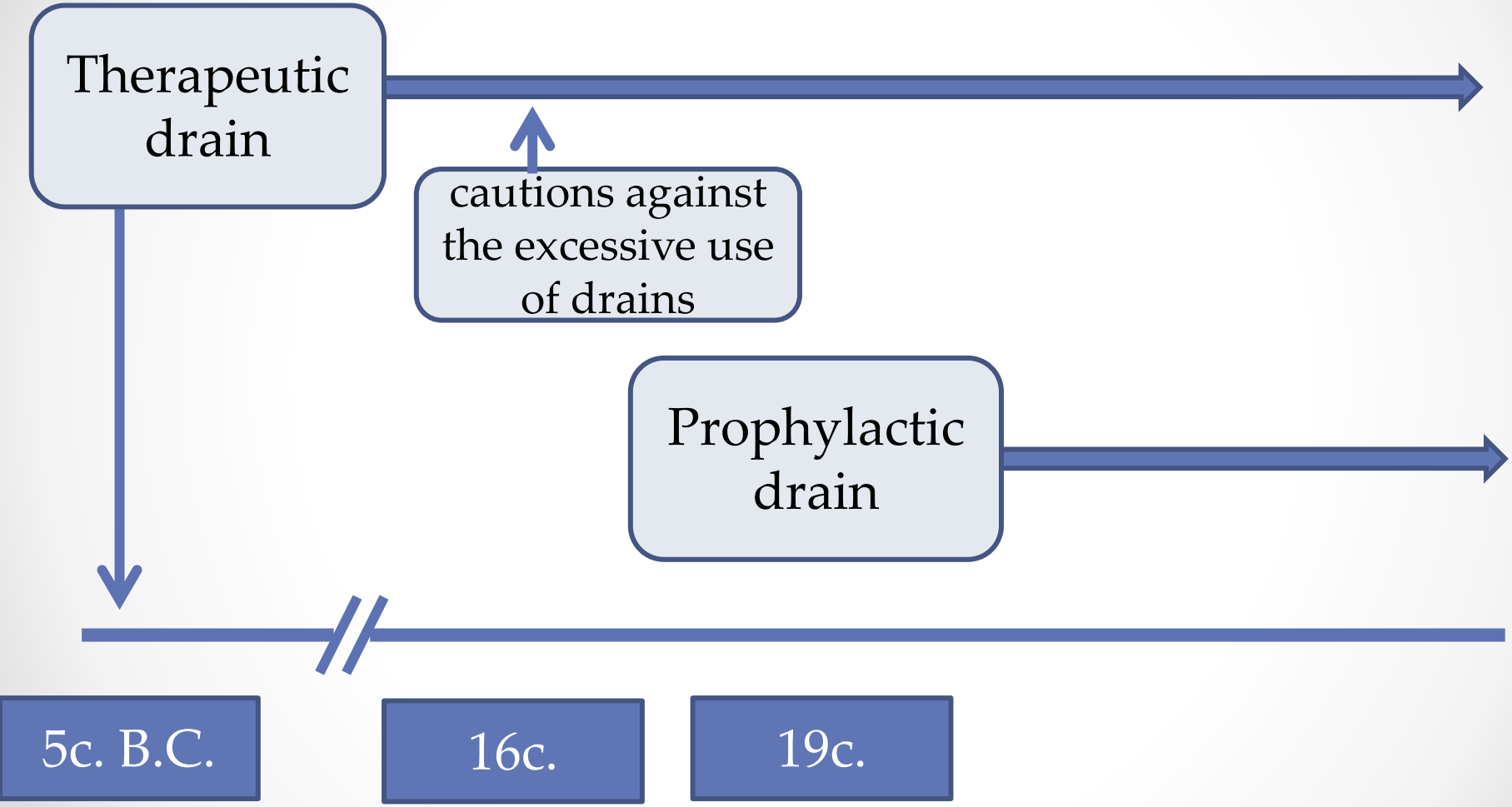
How should we use prophylactic drains ?

Drain: place in anticipation of an intra-peritoneal fluid collection

The presence of fluid or devitalized tissue in wounds inhibits the ability of normal host defence

There is evidence both in favor of and against the usefulness of prophylactic drainage

Institution	Journal	Study design	Group	Backgroud	Day of drain removal	Mortality	Overall comp	Re-admission	Re-intervention
MSKCC	Ann Surg 2001	RCT (PD+DP)	No drain (n=91)	No difference	none	2%	57%	11%	8%
			Drain (n=88)		POD-6 (2-26)	2%	63%	22%	13%
Houston	HPB 2011	Cohort (PD+DP)	No drain (n=47)	Internal stenting 57%*	none	1%	47%* (PF/DGE/w. infection)	17%	11%
			Drain (n=179)	28% ↓	NA	1%	65%	9%*	2%*

				d	drain removal	ality	comp	admission	intervention
France	WJ Surg 2013	Matched control	No drain (n=27)	No difference	none	3.7%	56% (PF 0%*)	3.7%	3.7%
			Drain (n=27)		At least 5 days	3.7%	70% (PF 22%)	0%	3.7%
MSKCC	Ann Surg 2013	Surgeon's choice (PD)	No drain (n=353)	EBL/Op time	None	3%	G3/4 30% PF 17%*	21%*	14%
			Drain (n=386)		NA	1%*	36% 27%	28%	18%
Emory	JACS 2013	Surgeon's choice (PD)	No drain (n=458)	PpPD/PV resection/ Op time/EBL/ duct size	None	30days 2.5%	54%*	16.8%	6.3% Re-op 5.7%
			Drain (n=251)		NA	2.0%	68%	17.5%	8.4% Re-op 5.6%

History of Drains and Drainage Procedures