PAIN-OUT

Improvement in Postoperative PAIN OUTcome

PAIN-OUT: An International Registry for Acute Postoperative Pain and a Platform for Studying Acute to Chronic Pain Transition

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Introduction and Background

Risk factors for the progression of acute pain after surgery to Chronic Post Surgical Pain (CPSP) are multi-factorial[1].
Pre-operative pain and severe post-operative pain are two recognized risk factors for developing CPSP. Most studies to date report data from single institutions, focus on a single type of surgery, and have a modest sample size. A comprehensive, multi-factorial investigation of CPSP should, ideally, draw upon a large-scale, continuously growing, database that is comprehensive, multi-center, and international. An International Acute Pain Registry can make this possible.

PAIN-OUT is a clinical research project designed to develop an effective, evidence-based approach to improving the care of patients in pain after surgery by creating an International Acute Pain Registry and developing tools for data collection, feedback and benchmarking and decision support (www.pain-out.eu). Launched in January 2009, with 4-year funding from the European Union's (EU) 7th Framework Program, the project involves 17 clinical and research partners in 9 European countries, a small number of sites outside of the EU have also joined.

Objectives:

1. Preliminary assessment of current data in the Registry looking at two of the known vulnerabilities for developing CPSP: pain *before* surgery, severe pain *after* surgery.

2. Offer the Registry as a platform for additional studies to improve understanding of CPSP.

Methods

Creating the Acute Pain Registry and data collection tools

During the first year of PAIN-OUT we carried out a Delphi-like process to consent on data items for the Registry. After this we created: (1) the project questionnaires. *Process* looking at e.g. patient demographics, information on surgery and analgesics given from before surgery until back on ward and *Outcomes,* looking at e.g. pain and interference, side effects and satisfaction and (2) web-based masks for data input and feedback. Process data is obtained from the patient's medical record. Patients fill in the Outcomes questionnaire on their own.

The Outcomes questionnaire is based on the American Pain Society's POQ-R[3]

The source Outcomes questionnaire was translated from English to Italian, German, French, Swedish, Korean, Russian, Spanish, Arabic, Romanian, Hebrew, Mandarin and Bahasa Malaysia. Additional languages will be added as the need arises.

Data collection started in February 2010, data is now collected regularly in 13 hospitals throughout Europe, US and Malaysia.

Patients are included if they are ≥18 years old, able to give consent for participation, able to fill in the Outcomes questionnaire within 24 hours after surgery.

Outcomes questionnaire

The questionnaire is currently undergoing validation. Here we show only 3 questions related to the 'Objectives' and which ask patients to assess:

1

P2. On this scale, please indicate the **worst pain** you had in the first 24 hours:

0	1	2	3	4	5	6	7	8	9	10

no pain — **worst pain possible**

2

P3. How often were you in **severe** pain in the first 24 hours?
Please circle your best estimate of the percentage of time you experienced severe pain:

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

never in severe pain — **always in severe pain**

3

P17. Did you have a **persistent painful condition** for three months or more before coming into hospital for this operation?

☐ No ☐ Yes

a. If yes, **how severe** was the pain most of the time?
Please circle the number that indicates this.

0	1	2	3	4	5	6	7	8	9	10

No pain — **Pain as bad as you can imagine**

b. If yes, where was this persistent pain located?

☐ site of surgery
☐ elsewhere
☐ both (site of surgery and elsewhere)

SEVENTH FRAMEWORK PROGRAMME

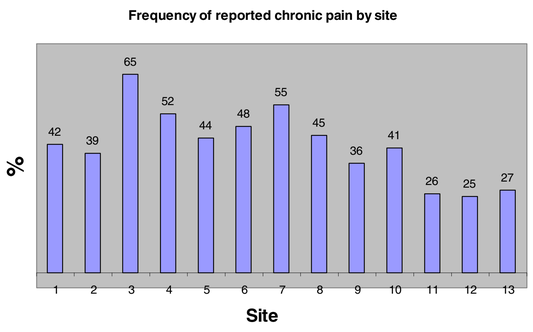
Results

On the 6th Septmber, 2010, data from 4122 patients was entered into the registry, of these 3163 data sets had valid data about existence of persistant pain before surgery :

43.8% reported **pain before surgery**, with **intensity** 6.0 ± 2.7 (mean, STD).
Site of the persistant pain (n=1375) (*in decsending order of frequency*) :
site of surgery (56.7%) > both (28.9%) > elsewhere (12.3%).

Fig1 shows how the frequencies of persistent pain before surgery are distributed in the different sites, internationally.

Fig 1



To assess relationship of pain before surgery *vs.* after, we looked at two specialities: patients after general (n = 1420) and orthopedic surgery (n = 1442).

Frequency of persistent pain *before* surgery: General surgery 35% (n = 503) *vs.* 57% (n = 828) orthopedic patients. (P < ,000).

Intensity of persistent pain *before* surgery: General surgery 5.98 (±2.786) *vs.* Orthopedic 6.09 (±2.603) (not significant).

Pain *after* surgery:

SPECIALTY	Question	Persistent BEFORE	N	Mean	Std. Deviation	Significant
General Surgery	Worst pain in 24 hrs	NO	917	5,10	2,971	*
		YES	503	5,50	2,966	
	Time in severe pain	NO	917	,203	,3104	NS
		YES	503	,192	,3835	
Orthopedics	Worst pain in 24 hrs	NO	612	5,90	2,876	*
		YES	828	6,25	2,827	
	Time in severe pain	NO	613	,279	,3407	NS
		YES	827	,287	,4156	

Summary

Many of patients in our sample reported persistent pain before surgery, and these patients reported higher levels of post-operative pain compared to patients without persistent pain. The differences are statistically significant but not necessarily clinically relevant.
The great majority of these patients underwent orthopedic surgery.
We still do not know how many of these patients will develop CPSP.

One of us (Dominique Fletcher) is leading an application to study CPSP in PAIN-OUT collaborating centers and additional centers, who are members of European Society of Anaethesia (ESA). This study will follow patients 24 hrs after surgery, at 6 & 12 months and assess whether patients developed a chronic pain condition. All the study tools will be provided by PAIN-OUT. If you are interested, please contact Dr Fletcher at: dominique.fletcher@rpc.aphp.fr

We hope that the Registry will provide a platform for studying CPSP on an international basis following patients after a large variety of surgeries, to further define risk factors for CPSP.

References

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3. Gordon et al Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R) for Quality Improvement of Pain Management in Hospitalized Adults. The Journal of Pain, 2010