

WS2
**EVIDENCE IN PAIN THERAPY FROM A SOCIETAL
PERSPECTIVE**

**PAIN UNDERTREATMENT IN
ONCOLOGICAL PATIENTS**

CERP
CENTER FOR THE RESEARCH & EVALUATION
OF CANCER

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BACKGROUND

PAIN AFFLICTS MOST OF CANCER PATIENTS

**DESPITE EVIDENCE FROM RESEARCH AND GUIDELINES,
UP TO 40% ARE UNDERTREATED**

**AMONG SEVERAL CAUSES, MOST ARE RELATED TO
INCORRECT USE (UNDEPRESCRIPTION) OF OPIOIDS**

THIS PHENOMENON IS QUITE RELEVANT IN ITALY

THE ITALIAN CONTEXT

IN ITALY, THE EPIDEMIOLOGY OF CANCER PAIN ALTHOUGH NOT FULLY DESCRIBED, IS NOT DIFFERENT THAN IN OTHER EUROPEAN COUNTRIES

THE PRESCRIPTION OF WHO-III ANALGESIC DRUGS IN ITALY IS ONE OF THE LOWEST IN THE OCCIDENTAL WORLD

THUS, UNDERTREATMENT CAN BE EXPECTED, AND THERE IS A NEED FOR IMPROVEMENT

QUALITY OF ANALGESIC TREATMENTS

- **RESULTS FROM A SYSTEMATIC REVIEW OF LITERATURE (1)**
- **UTILIZATION OF A STANDARDIZED QUALITY MEASURE (PMI) ON AN ITALIAN SAMPLE (2)**
- **APPLICATION OF A SELECT LIST OF CLINICAL INDICATORS ON THE SAME SAMPLE (2,3)**

1) S. DEANDREA et al. *Annals of Oncology*, 19: 1985-91, 2008

2) G. APOLONE et al, *British Journal of Cancer*, 100:1566-74, 2009

3) MT GRECO et al, *Clinical Journal of Pain*, Submitted

SYSTEMATIC REVIEW

A SYSTEMATIC REVIEW OF LITERATURE WAS CARRIED OUT WITH TWO OBJECTIVES:

- TO IDENTIFY A STANDARDISED (VALID AND RELIABLE) TOOL TO MEASURE QUALITY OF ANALGESIC CARE, and**
- TO ESTIMATE THE PREVALENCE OF UNDERTREATMENT ACROSS STUDIES**

WE IDENTIFIED 44 STUDIES USING A STANDARDIZED TOOL, AND 26 USED THE SAME INSTRUMENT: THE CLEELAND PMI

9 STUDIES WERE FROM EUROPE (FROM 1999 TO 2009)

PAIN MANAGEMENT INDEX

BY CLEELAND AT AL, NEJM 1994

WHO ANALGESIC DRUG LEVEL					
	PAIN INTENSITY	0	1	2	3
		no drugs	no opioids	weak opioids	strong opioids
0	no pain (0)	0	+1	+2	+3
1	mild (1-3)	-1	0	+1	+2
2	moderate (4-7)	-2	-1	0	+1
3	severe (≥ 8)	-3	-2	-1	0

PAIN MANAGEMENT INDEX

BY CLEELAND AT AL, NEJM 1994

PAIN MANAGEMENT INDEX (PMI) COMPARES THE MOST POTENT ANALGESIC PRESCRIBED FOR PATIENTS WITH THE PATIENTS' REPORTED LEVEL OF WORST PAIN

PMI MAY BE CONSIDERED ONLY A PRELIMINARY INDICATOR (A SCREENER) OF POTENTIAL UNDERTREATMENT AS IT DOES NOT CONSIDER THE DOSE ACTUALLY ADMINISTERED, THE COMPLIANCE, THE USE OF RESCUE AND ADJUVANT TREATMENTS, THE USE OF NON-PHARMACOLOGICAL THERAPIES.

IN ADDITION, IT IS A TOOL THAT IS NOT VALID AND SENSITIVE ENOUGH TO BE USED AT INDIVIDUAL LEVEL

FINALLY, IT IS APPROPRIATE ONLY FOR CROSS-SECTIONAL UTILIZATION.

RESULTS

**RANGE OF UNDERTREATMENT VARIED FROM 7 TO 82%
(WEIGHTED MEAN: 43%)**

**SEVERAL FACTORS SHOWN TO BE ASSOCIATED WITH
UNDERTREATMENT AT UNIVARIATE ANALYSIS**

**AFTER CONTROLLING FOR CONFOUNDERS (MULTIVARIABLE
ANALYSIS) ONLY A FEW KEPT STATISTICAL SIGNIFICANCE:
STUDIES BEFORE 2001, FROM EUROPE AND ASIA, COUNTRIES
WITH GNP < 40.000 \$, SETTING OF CARE**

UNDERTREATMENT IN EUROPE

S. De Andrea, et al Annals of Oncology,2008

<i>Year</i>	<i>Country</i>	<i>No. Cases</i>	<i>%</i>
<i>1995</i>	<i>France</i>	<i>270</i>	<i>51</i>
<i>1999</i>	<i>Netherlands</i>	<i>313</i>	<i>49</i>
<i>2001</i>	<i>Greece</i>	<i>220</i>	<i>76</i>
<i>2001</i>	<i>Germany</i>	<i>905</i>	<i>13</i>
<i>2003</i>	<i>Italy</i>	<i>117</i>	<i>43</i>
<i>2004</i>	<i>Italy</i>	<i>752</i>	<i>82</i>
<i>2006</i>	<i>UK</i>	<i>864</i>	<i>7-9</i>
<i>2007</i>	<i>Netherlands</i>	<i>244</i>	<i>65</i>
<i>2009</i>	<i>Italy</i>	<i>1801</i>	<i>21-45</i>

DETAILS OF RESULTS

Characteristics of studies	No. of studies	Range of negative PMI (%)	Standard deviation	Median	Weighted mean
Year					
1994–2000	12	27–79	18.47	46.5	46.6
2001–2007	14	8–82	26.33	60.0	41.5
Geographic area					
United States	8	8–65	19.14	33.0	39.1
Europe	8	9–82	26.62	51.0	40.3
Asia	9	27–79	17.47	69.0	59.1
Economic level					
GNI per capita < \$20 000	8	31–79	17.37	68.0	53.7
GNI per capita \$20 000–\$40 000	7	13–82	25.75	51.0	48.2
GNI per capita ≥\$40 000	11	8–65	20.72	37.0	34.2
Setting ^a					
Specific for cancer patients or hospice ^b	15	8–79	21.33	53.5	52.2
Not specific ^b	5	29–74	23.45	46.5	42.8
Mixed	5	9–82	27.00	58.0	44.6
Stage of disease ^a					
At least 68.8% metastatic	8	13–65	16.54	39.5	31.2
<68.8% metastatic	12	29–82	17.75	66.0	58.4
Mean age of the sample ^a					
≥58 years old	11	27–79	19.62	65.0	55.1
<57 years old	11	8–82	21.52	43.0	53.6
Total	26	8–82	22.63	51	43.40

THE OR STUDY

Health and Quality of Life Outcomes



Research

Open Access

Pain in cancer. An outcome research project to evaluate the epidemiology, the quality and the effects of pain treatment in cancer patients

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SPECIFIC OBJECTIVES

TO DESCRIBE THE EPIDEMIOLOGIC CHARACTERISTICS OF A LARGE COHORT OF CANCER PATIENTS SEEKING ANALGESIC CARE IN ITALIAN CENTERS

TO EVALUATE THE QUALITY (APPROPRIATENESS) OF ANALGESIC TREATMENTS DELIVERED

TO EVALUATE THE EFFECTIVENESS OF ALTERNATIVE ANALGESIC STRATEGIES (USING THE PROPENSITY SCORE METHOD TO ADJUST FOR CONFOUNDING FACTORS), WITH SPECIAL EMPHASIS ON BUP TDS

TO EVALUATE THE YIELD OF DIFFERENT METHODS TO ASSESS PAIN IN CLINICAL RESEARCH

STUDY DESIGN

**AN OBSERVATIONAL, MULTI-CENTER, COHORT,
PROSPECTIVE, OPEN-LABEL, LONGITUDINAL STUDY**

**INCLUDING ADVANCED/METASTATIC CANCER PATIENTS
WITH PAIN**

EVALUATIONS AT BASELINE, AND 7,14,21,28, 84 DAYS

**EACH CENTER RECRUITED A MAXIMUM OF 25 CONSECUTIVE
CASES, DURING 2 MONTHS**

**DATA COLLECTION THROUGH A WEB-BASED ELECTRONIC
CRF**

CENTRAL DATA MONITORING AND COORDINATION

PILOT STUDY ON 130 CENTERS (2006)

RECRUITMENT

RECRUITMENT FROM MARCH 2006 TO MARCH 2007

123 CENTRES RECRUITED 1930 PATIENTS

LAST PATIENT LAST VISIT BY JULY 2007

AVERAGE RECRUITMENT: 15 CASES

CENTERS WITH 25 CASES: 35

VALID CENTER/CASES AFTER EXCLUSIONS: 110/1802

BASELINE CHARACTERISTICS ON 1.801

AGE, mean (SD)	63.9 (12.1)
MALE, %	53
KPS <50, %	11.5
LUNG, %	22
BREAST CANCER,%	16
COLO-RECTAL CANCER,%	14
BONE METASTASIS,%	47

BASELINE CHARACTERISTICS

CONT'

	%
TYPE OF WARDS	
- ONCOLOGY	59
- PALLIATIVE UNIT	17
- PAIN CENTER	15
- HOSPICE	8
- OTHER	1
LEVEL OF INFORMATION	
- PROGNOSIS	31
ANTI-CANCER TREATMENTS	49

PMI IN ITALY, 1801 CASES

NEGATIVE PMI
%

NEGATIVE PMI (ALL CASES)

25.3

NEGATIVE PMI IN NEW CASES

45.0

NEGATIVE PMI ACCORDING TO SEVEARL FACTORS:

TYPE OF CENTERS

17.4 - 33.3

TYPE OF CANCERS

20.2 - 31.7

BONE METASTASIS

22.3-27.9

ADJUVANT THERAPY

18.1-36.0

AGE

22.8-28.0

MULTIVARIATE ANALYSIS

	OR	95% CI
TYPE OF RECRUITING CENTER		
- Hospice	1.0	--
- Palliative and Pain Center	2.1	1.3-3.4
- Oncology	2.1	1.2-3.5
TYPE OF PATIENTS		
- Old cases	1.0	--
- New cases	2.5	1.9-3.2
AJUVANT THERAPY		
- Yes	1.0	--
- No	2.4	1.9-3.0

ADDITIONAL QUALITY MEASURES

AS PMI AT THE BEST MAY BE CONSIDERED ONLY A SCREENER OF POTENTIAL UNDERTREATMENT, WE ALSO USED A *A-PRIORI* SELECTED LIST OF INDICATORS TO CAPTURE THE CLINICAL APPROPRIATENESS OF THE ANALGESIC CARE DELIVERED :

- BTcP SHOULD BE TREATED WITH RESCUE/ESCAPE THERAPY,
- NEUROPATHIC PAIN SHOULD BE TREATED WITH ADJUVANT DRUGS
- BONE METASTASIS SHOULD BE TREATED WITH BISPHOSPHONATES,
- PAIN INTENSITY >7 TO BE TREATED WITH WHO LEVEL III DRUGS

OTHER QUALITY INDICATORS

PROPORTION OF PTS. RECEIVING 4 RECOMMENDED TREATMENTS

%

RESCUE THERAPY IN BTCp 23.8

SPECIFIC TREATMENTS IN NEUROPHATIC PAIN 44.6

BISPHOSPHONATES IN BONE METASTASIS 38.0

A STRONG OPIOID IN WORST PAIN > 7 (NRS) 59.1

WARNINGS

MOST RESULTS ARE FROM ITALY

PMI IS ONLY A COARSE INDICATOR OF UNDER-TREATMENT

RECOMMENDED TREATMENTS MAY BE QUESTIONABLE

**SOME RESULTS ARE STILL UNDER REVISION
(SUBMITTED)**

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