



X CONGRESSO GAVECELT

FIRENZE 4-5 DICEMBRE 2017

PORT E ACCESSI VENOSI IN ONCOLOGIA

DISPOSITIVI PER ACCESSO VENOSO NEL PAZIENTE IN TRATTAMENTO
CHEMIOTERAPICO: QUALITÀ DI VITA ED IMPATTO PSICOLOGICO

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Altan

GLI SCHELETRI VANNO
CONSERVATI IN
CASSAFORTE, NON
NEGLI ARMADI.



“Scheletri
negli
armadi”

L'Espresso
28 mag 2017

Disclosures

- Dr Biffi has been Consultant/Advisory Board Member 2012 for Carefusion Italy srl, Sesto Fiorentino.
- He obtained technical support for conducting RCTs by Bard Italy, Rome ; B. Braun SpA, Milan; and ConvaTEC Inc., Princeton, NJ.
- He received unrestricted educational grants from these Firms /Companies: Bard Italy, B. Braun Italy, Covidien-Medtronic Italy, Ethicon Endosurgery, Johnson & Johnson Italy, 3M Italy and Public Charities.
- Part of the investigational results here presented was supported by a research grant of AIRC (Associazione Italiana per la Ricerca sul Cancro = Italian Cancer Research Foundation); Grant # 1126.

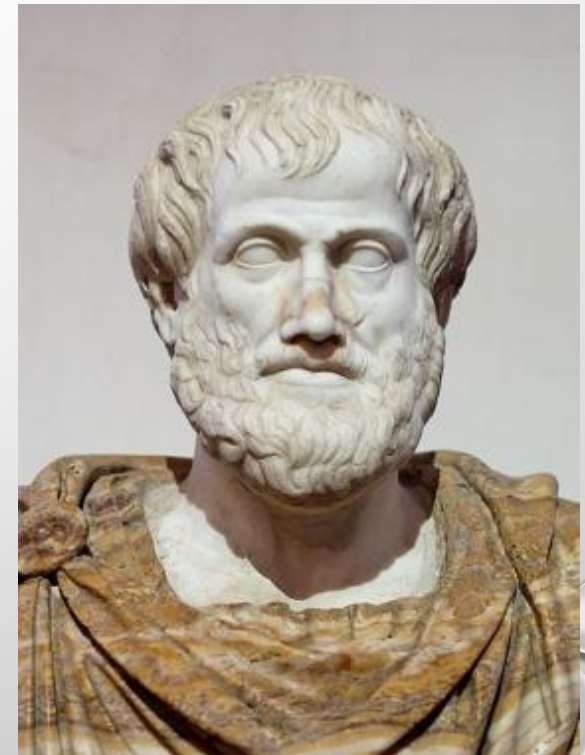
Il termine **qualità di vita** (o favorevoli condizioni di vita) indica il benessere di uno o più individui, non necessariamente della stessa specie, di un habitat, ambiente di lavoro, una comunità, città o nazione.

Fonte: Wikipedia

Comunità di pazienti oncologici

Il dibattito sulla qualità di vita è antico. Già Aristotele lo ha trattato nell'*Etica Nicomachea*, usando il concetto di *eudaimonia*, che in greco significa

"buon spirito" .



In una serie di articoli pubblicati qualche anno fa sul *British Medical Journal*, la qualità della vita di una persona malata di cancro veniva definita come lo **“scollamento tra ciò che il paziente immagina e la realtà che si trova a vivere”**.

"Ognuno vive la malattia a modo suo, in base alla propria storia, alla propria condizione, al tipo di malattia, e per questo le conseguenze della perdita della salute sono estremamente variabili, anche se ciò non significa che non si possa attuare una misurazione anche di questi parametri" .

Giorgio Bert, psicologo, fondatore dell'Istituto di counseling CHANGE di Torino

Nel 1996, l' ASCO ha inserito la qualità della vita, insieme alla sopravvivenza e alla tossicità, nella lista dei cosiddetti **hard end-points**, cioè di quegli elementi che si devono assolutamente considerare nel giudicare l'efficacia di un farmaco, e che possono essere di per sé motivo per una sperimentazione clinica.

ELEMENTI MISURABILI DELLA QUALITA' DI VITA NEL PAZIENTE ONCOLOGICO

Domanda-chiave:

Come è possibile misurare un parametro che è in gran parte costituito dalle peculiarità di ogni singolo paziente? Quali sono gli strumenti oggi utilizzati? RECIST?

Gli strumenti che misurano la QoL sono **questionari** che pongono domande su come il paziente percepisce la propria condizione rispetto ad aspetti fisici della vita (per esempio la capacità di camminare, di salire le scale, di svolgere lavori), o ad aspetti psicologici, sociali ed economici.

“ Non c'è dubbio che è necessario poter disporre di dati affidabili sulla qualità di vita, e che ciò aiuta chi è destinato a valutare la bontà delle nuove cure. **Bisogna stare attenti, però, perché è molto più difficile garantire una buona qualità di analisi dei dati per questo parametro così particolare rispetto, per esempio, a misurare in modo univoco per quanto tempo i malati sopravvivono, e questo potrebbe generare pericolosi fraintendimenti ed errori**” *.

* Fonte: F Perrone per AIRC 2015.



QLQ C 30

EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER QUALITY OF LIFE
QUESTIONNAIRE - CORE 30 – QUESTIONS.

- MANY EFFORTS WERE MADE IN ONCOLOGY TO ESTABLISH QUALITY-OF-LIFE RESEARCH WITHIN CLINICAL TRIALS.
 - THE FIRST STEP WAS TO INTRODUCE RESEARCH QUESTIONS REGARDING THE QUALITY OF LIFE (QOL) OF PATIENTS INTO THE CLINICAL TRIALS.
 - QLQ C 30 QUESTIONNAIRE PROVIDED BY THE EORTC QUALITY OF LIFE STUDY GROUP IS A **VALID AND RELIABLE STANDARD INSTRUMENT FOR QOL EVALUATION** .
 - ALTHOUGH QOL IS MENTIONED MORE AND MORE AS A PRIMARY OR SECONDARY ENDPOINT, THE NUMBER OF INVESTIGATIONS THAT ACTUALLY EMPLOY QOL FOR ANSWERING CLINICALLY RELEVANT QUESTIONS IS STILL VERY LIMITED (IN SPITE OF HIGH COST, ESPECIALLY IN ONCOLOGY SETTING).
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QLQ C 30

EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER QUALITY OF LIFE
QUESTIONNAIRE - CORE 30 – QUESTIONS.

STRENGTH: RELIABLE, REPRODUCIBLE, VALIDATED IN DIFFERENT SETTINGS AND CULTURES.

WEAKNESS: POORLY APPLICABLE TO THE VADS WORLD, WHERE SPECIFICITY IS REQUIRED, SIMILARLY
TO QUESTIONNAIRES APPLIED TO H&N, GYN, G-I AND SO ON .



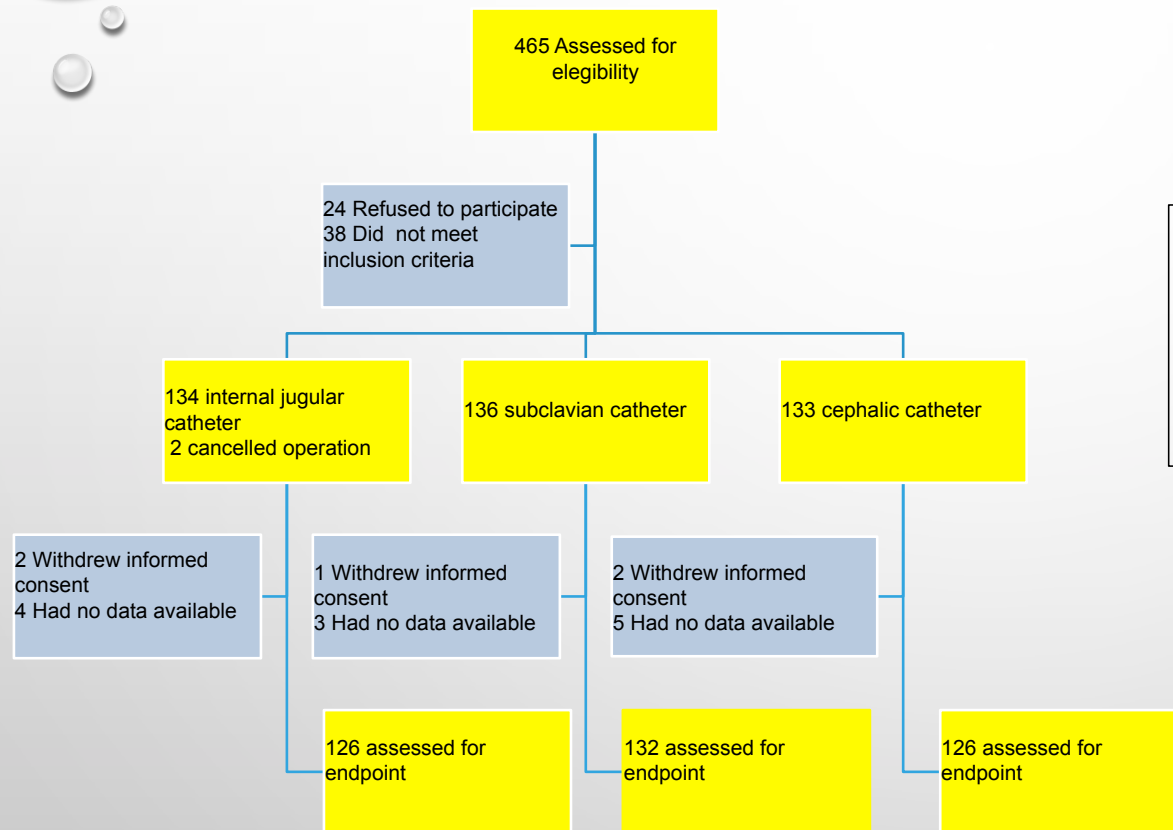
**No impact of central venous insertion site
on oncology patients' quality of life and psychological distress.
A randomized three-arm trial.**

Biffi R, Orsi F, Pozzi S, Maldifassi A, Radice D, Rotmensz N,
Zampino MG, Fazio N, Peruzzotti G, Didier F.

Support Care Cancer 2011 Oct;19(10):1573-80.
doi: 10.1007/s00520-010-0984-9.



Trial profile conforming to the CONSORT guidelines



**No impact of central venous insertion site
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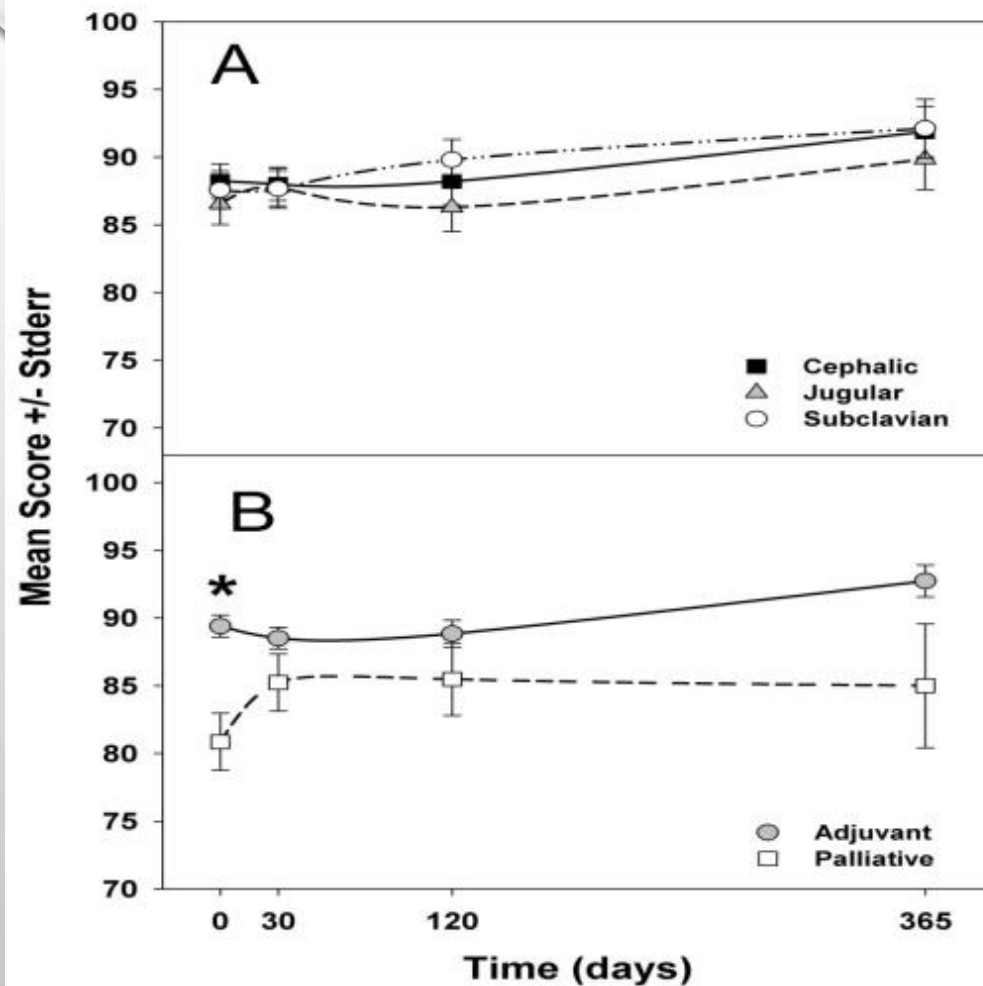
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Implantation site	Adjuvant	Palliation
Cephalic , no. (%)	94 (74.6)	32 (25,4)
Internal jugular ,no.(%)	93 (73.8)	33 (26.2)
Subclavian, no. (%)	102 (77.3)	30 (22,7)
Total (383)	289	95

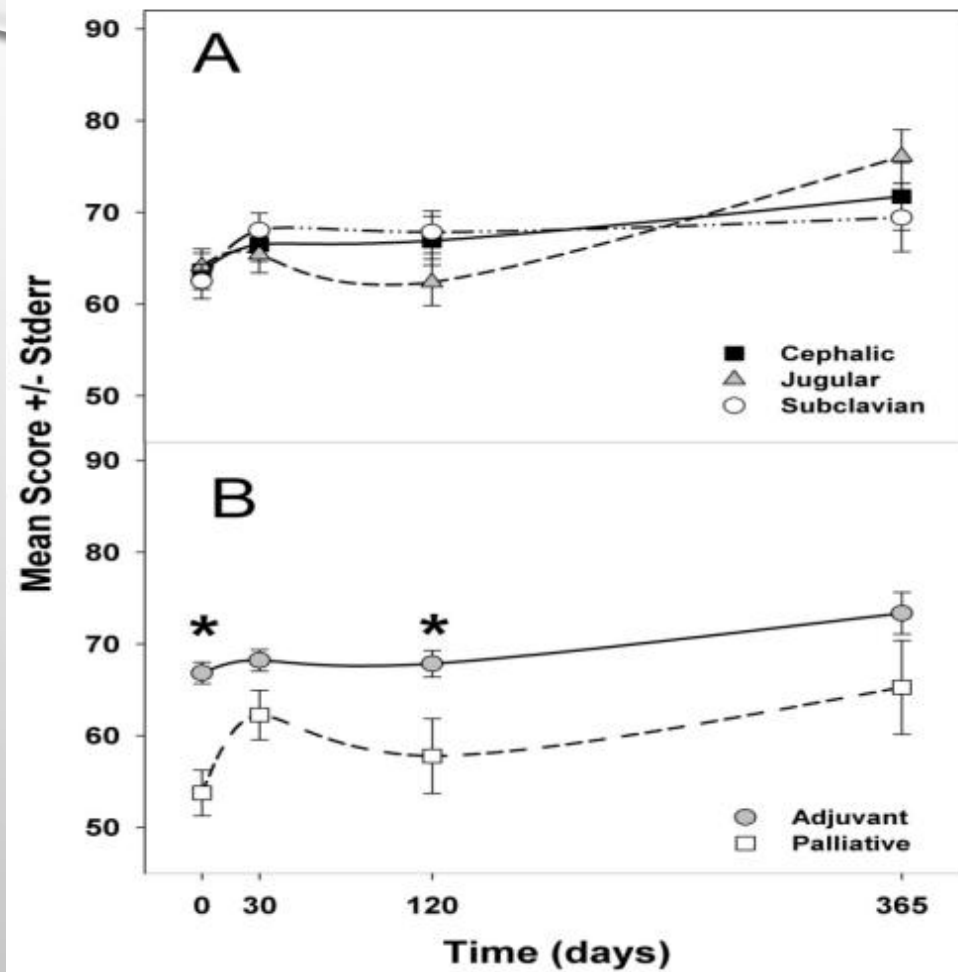
No impact of central venous insertion site on oncology patients' quality of life and psychological distress. A randomized three-arm trial.

R Biffi et al R, Support Care Cancer 2011



Physical Functioning – QLQ C 30

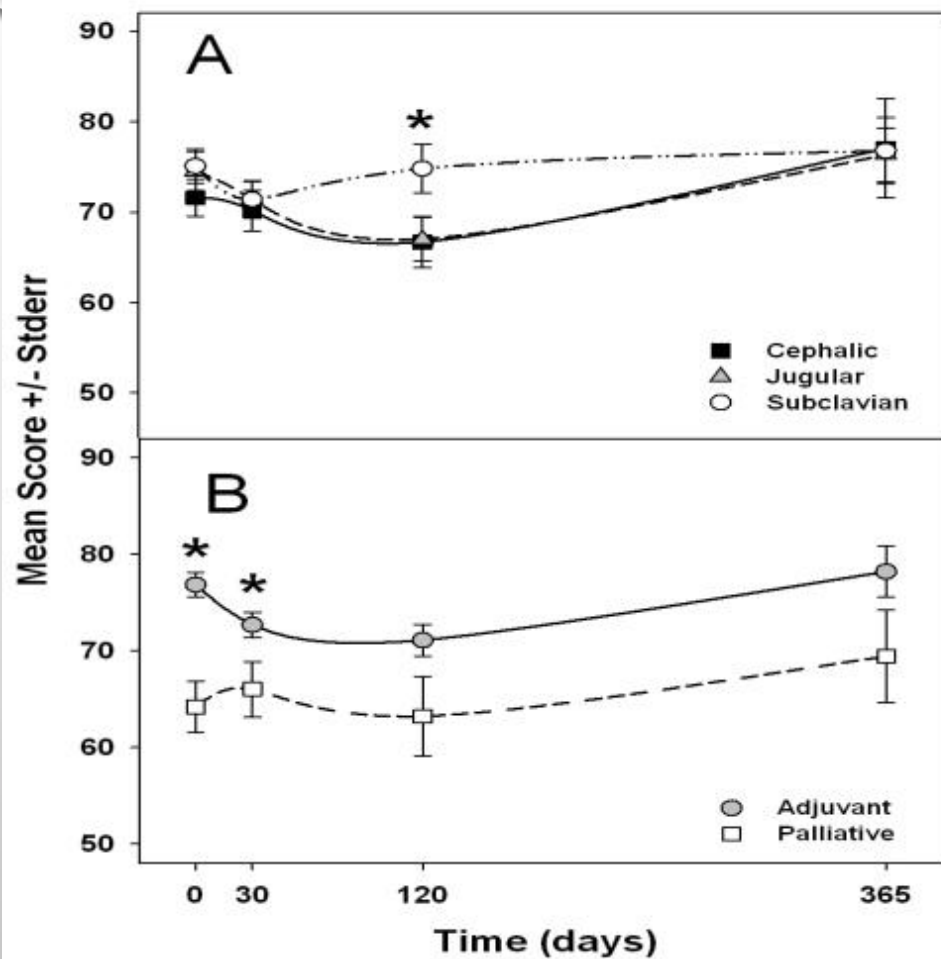
EORTC Physical Functioning score by Time according to (A) TIAP and (B) Chemotherapy. There was a significant difference between Adjuvant and Palliative treatments at baseline ($P < 0.001$) but not at 30, 120 and 365 days.



Global Health – QLQ C 30

EORTC Global Health score by Time according to (A) TIAP and (B) Chemotherapy.

There was a significant difference between Adjuvant and Palliative treatments at baseline ($P < 0.001$) and at 120 days ($P = 0.046$) but not at 30 and 365 days.

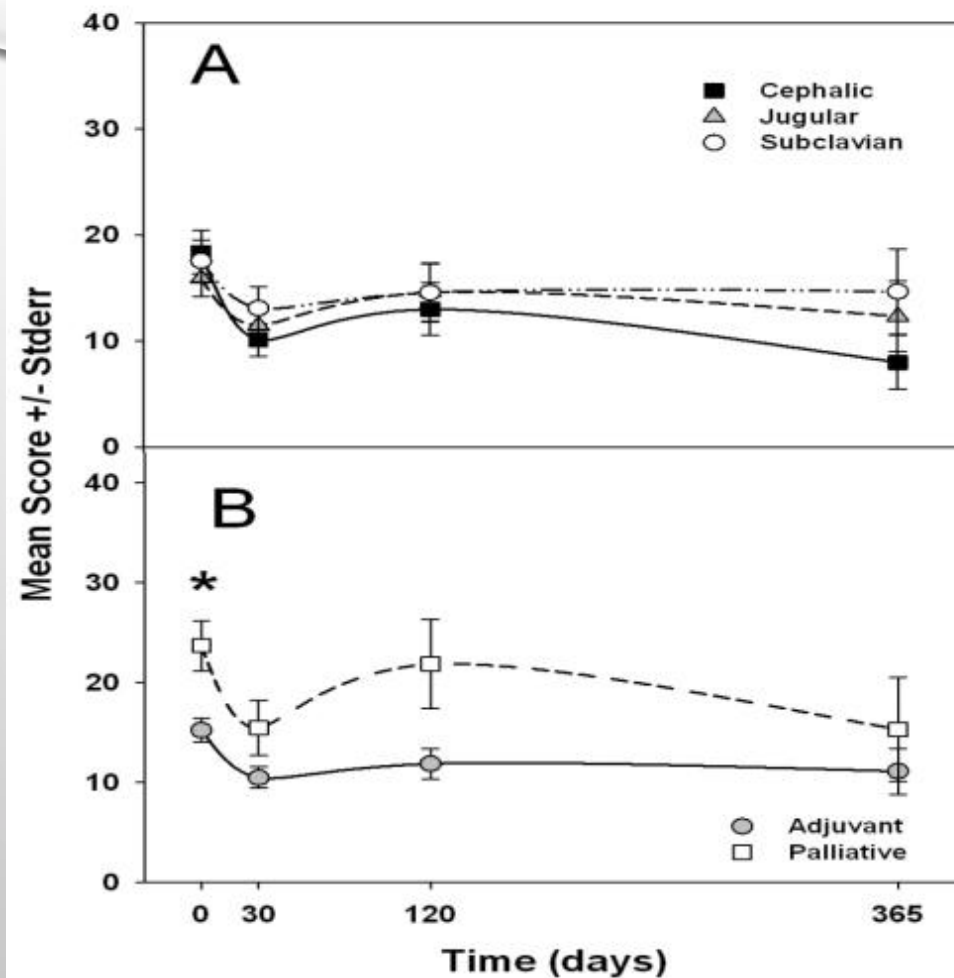


Fatigue – QLQ C 30

EORTC Fatigue score by Time according to (A) TIAP and (B) Chemotherapy.

There was a significant difference between Adjuvant and Palliative treatments at baseline ($P < 0.001$) and at 30 days ($P = 0.043$) but not at 120 and 365 days.

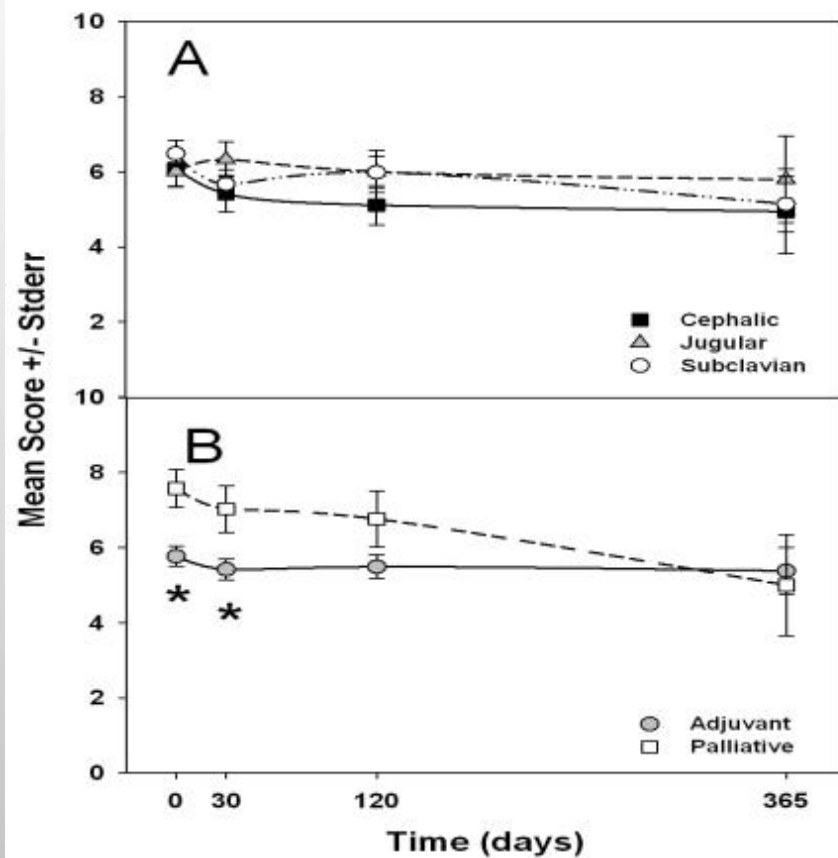
At 120 days Subclavian patients had a significantly higher Fatigue scores with respect to both Jugular and Cephatic patients.



Pain – QLQ C 30

EORTC Pain score by Time according to (A) TIAP and (B) Chemotherapy.

There was a significant difference between Adjuvant and Palliative treatments at baseline only (P = 0.002)



HADS - HOSPITAL ANXIETY AND DEPRESSION SCORE

HADS DEPRESSION MEAN SCORES BY TIME ACCORDING TO (A) TIAP AND (B) CHEMOTHERAPY.

THERE WERE SIGNIFICANT DIFFERENCE BETWEEN ADJUVANT AND PALLIATIVE TREATMENTS AT BASELINE ($P < 0.001$) AND AT 3 MONTHS ($P = 0.02$)



QASICC

BULL CABNCER 2015 APR;102(4):301-15. DOI: 10.1016/J.BULCAN.2015.02.012. EPUB 2015 MAR 21.

[MULTICENTER VALIDATION STUDY OF A QUESTIONNAIRE ASSESSING PATIENT SATISFACTION WITH AND ACCEPTANCE OF TOTALLY-IMPLANTED CENTRAL VENOUS ACCESS DEVICES].

[ARTICLE IN FRENCH]

MARCY PY, DHALET C, BERNET O ET AL

FRENCH-LANGUAGE QUESTIONNAIRE :

**QUESTIONNAIRE FOR ACCEPTANCE OF AND SATISFACTION WITH IMPLANTED
CENTRAL VENOUS CATHETER.**



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⁹UNITÉ DE RECHERCHE CLINIQUE, DÉPARTEMENT DE RECHERCHE CLINIQUE, INNOVATION ET STATISTIQUES, CENTRE ANTOINE-LACASSAGNE, 33, AVENUE DE VALOMBROSE, 06189 NICE CEDEX 02, FRANCE.

¹⁰UNITÉ D'ÉPIDÉMIOLOGIE ET DE BIOSTATISTIQUES, DÉPARTEMENT DE RECHERCHE CLINIQUE, INNOVATION ET STATISTIQUES, CENTRE ANTOINE-LACASSAGNE, 33, AVENUE DE VALOMBROSE, 06189 NICE CEDEX 02, FRANCE.

METHODOLOGY

FINAL QASICC TOOL INCLUDED **TWENTY-TWO QUESTIONS ASSESSING FOUR HOMOGENEOUS DIMENSIONS** ($65\% < \text{CRONBACH COEFFICIENT} < 85\%$):

- (i) IMPACT ON DAILY AND PROFESSIONAL ACTIVITIES;
- (ii) ESTHETICS AND PRIVACY;
- (iii) PAIN, CONTRIBUTION TO THE COMFORT OF THE TREATMENT;
- (iv) LOCAL DISCOMFORT.

OVERALL SATISFACTION SCORE WAS 75.8%;

GLOBAL ASSESSMENT SCORE WAS 76.2%.

THESE SCORES WERE SIGNIFICANTLY LINKED TO PATIENT'S **GENDER, ANESTHESIA TYPE, TIVAD'S IMPLANTATION SIDE, PATIENT'S AGE AND TUMOR TYPE.**

CONCLUSIONS:

This second and final methodological and statistical validation of this auto-questionnaire QASICC allows the Authors to propose it as a dedicated questionnaire to TIVAD's cancer patients by using a score assessing acceptance and satisfaction regarding their device.

Comments: what about non-French and non-TIVADS patients ? Time interval checks?

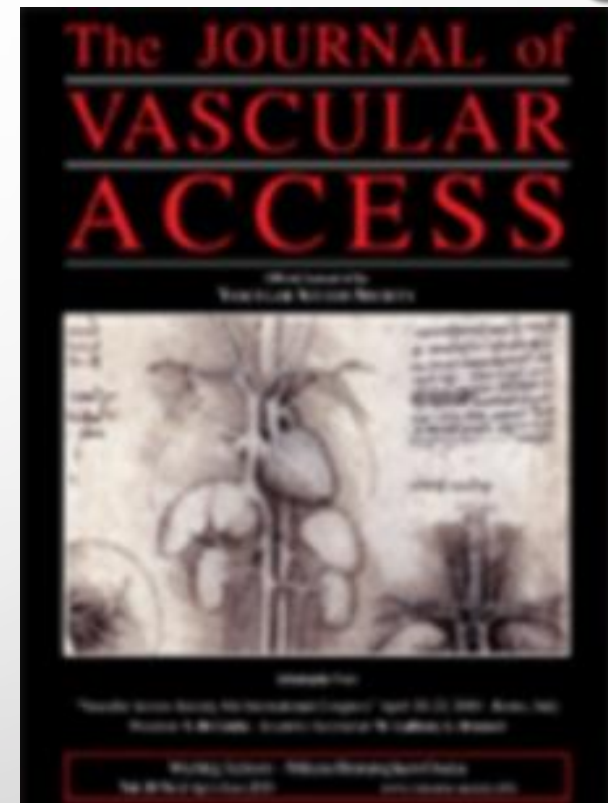
Patient satisfaction and acceptance of their totally implanted central venous catheter: a French prospective multicenter study.

Marcy PY, Schiappa R, Ferrero JM et al

J Vasc Access. 2017 Sep 11;18(5):390-395.

doi: 10.5301/jva.5000744.

Epub 2017 Jul 19



The questionnaire was submitted to 720 patients in 11 French institutions; 567 answers were analyzed.

Younger patients had the most difficulties in coping with their TIVAD, especially regarding daily activities and their body image and private life compared to older patients. Sex was significantly related to patient satisfaction, with worse scores in women. Breast tumor location was also correlated with low TIVAD acceptance.

CONCLUSIONS:

QASICC has proved to be efficient, and to detect known issues regarding daily activities and body image. The TIVAD remains generally well-accepted and our questionnaire should help health-care workers to better address the specific needs of their patients based on the answers provided.

As our population was mostly composed of women with breast cancer, our results reflect specific aspects of this population.



WOCOVA 2016 DEBATE SESSION: QUALITY OF LIFE

**QUESTION 2 : DO YOU BELIEVE THAT UNDERLYING DISEASE AND/OR TUMOUR STAGE INFLUENCES
QOL MORE THAN THE CHOICE OF THE VAD?**

yes



WOCOVA 2016 DEBATE SESSION: QUALITY OF LIFE

CONCLUSION:

WHILE WAITING FOR FURTHER EVIDENCES, A PROPER ASSESSMENT OF CLINICAL SETTING AND PATIENTS' CHARACTERISTICS IS NEEDED TO CORRECTLY PROGRAM NEW RCTS ON QOL IN VADS CARRIERS, BECAUSE BASELINE/SEQUENTIAL TIME DIFFERENCES ARE SIGNIFICANT AMONG PATIENTS POPULATIONS, AND HOMOGENEOUS GROUPS SHOULD BE COMPARED.



GRAZIE DELLA VOSTRA
CORTESE ATTENZIONE

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