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18. Innovative haematological parameters for early diagnosis of sepsis in adult patients admitted in intensive care unit. ................................................................. Page 10
1. Development and optimization of transferrin-conjugated nanostructured lipid carriers for brain delivery of paclitaxel using Box–Behnken design.

Authors: Emami, Jaber; Rezazadeh, Mahboubeh; Sadeghi, Hojjat; Khadivar, Khashayar

Source: Pharmaceutical Development & Technology; May 2017; vol. 22 (no. 3); p. 370-382

Publication Date: May 2017

Abstract: The treatment of brain cancer remains one of the most difficult challenges in oncology. The purpose of this study was to develop transferrin-conjugated nanostructured lipid carriers (Tf-NLCs) for brain delivery of paclitaxel (PTX). PTX-loaded NLCs (PTX-NLCs) were prepared using solvent evaporation method and the impact of various formulation variables were assessed using Box–Behnken design. Optimized PTX-NLC was coupled with transferrin as targeting ligand and in vitro cytotoxicity of it was investigated against U-87 brain cancer cell line. As a result, 14.1 mg of cholesterol, 18.5 mg of triolein, and 0.5% poloxamer were used to prepare the optimal formulation. Mean particle size (PS), zeta potential (ZP), entrapment efficiency (EE), drug loading (DL), mean release time (MRT) of adopted formulation were confirmed to be 205.4 ± 11 nm, 25.7 ± 6.22 mV, 91.8 ± 0.5% , 5.38 ± 0.03% and 29.3 h, respectively. Following conjugation of optimized PTX-NLCs with transferrin, coupling efficiency was 21.3 mg transferrin per mmol of stearylamine; PS and MRT were increased while ZP, EE and DL decreased non-significantly. Tf-PTX-NLCs showed higher cytotoxic activity compared to non-targeted NLCs and free drug. These results indicated that the Tf-PTX-NLCs could potentially be exploited as a delivery system in brain cancer cells.

2. Cabazitaxel for Hormone-Relapsed Metastatic Prostate Cancer Previously Treated With a Docetaxel-Containing Regimen: An Evidence Review Group Perspective of a NICE Single Technology Appraisal.

Authors: Kearns, Benjamin; Pandor, Abdullah; Stevenson, Matt; Hamilton, Jean; Chambers, Duncan; Clowes, Mark; Graham, John; Kumar, M.; Kumar, M Satish

Source: PharmacoEconomics; Apr 2017; vol. 35 (no. 4); p. 415-424

Abstract: Cabazitaxel is a taxane derivative that is approved for the treatment of hormone-relapsed metastatic prostate cancer in patients previously treated with a docetaxel-containing regimen. This article provides an evidence review group perspective of a NICE single technology appraisal for cabazitaxel.
As part of its single technology appraisal (STA) process, the National Institute for Health and Care Excellence (NICE) invited the company that manufactures cabazitaxel (Jevtana®, Sanofi, UK) to submit evidence for the clinical and cost effectiveness of cabazitaxel for treatment of patients with metastatic hormone-relapsed prostate cancer (mHRPC) previously treated with a docetaxel-containing regimen. The School of Health and Related Research Technology Appraisal Group at the University of Sheffield was commissioned to act as the independent Evidence Review Group (ERG). The ERG produced a critical review of the evidence for the clinical and cost effectiveness of the technology based upon the company's submission to NICE. Clinical evidence for cabazitaxel was derived from a multinational randomised open-label phase III trial (TROPIC) of cabazitaxel plus prednisone or prednisolone compared with mitoxantrone plus prednisone or prednisolone, which was assumed to represent best supportive care. The NICE final scope identified a further three comparators: abiraterone in combination with prednisone or prednisolone; enzalutamide; and radium-223 dichloride for the subgroup of people with bone metastasis only (no visceral metastasis). The company did not consider radium-223 dichloride to be a relevant comparator. Neither abiraterone nor enzalutamide has been directly compared in a trial with cabazitaxel. Instead, clinical evidence was synthesised within a network meta-analysis (NMA). Results from TROPIC showed that cabazitaxel was associated with a statistically significant improvement in both overall survival and progression-free survival compared with mitoxantrone. Results from a random-effects NMA, as conducted by the company and updated by the ERG, indicated that there was no statistically significant difference between the three active treatments for both overall survival and progression-free survival. Utility data were not collected as part of the TROPIC trial, and were instead taken from the company's UK early access programme. Evidence on resource use came from the TROPIC trial, supplemented by both expert clinical opinion and a UK clinical audit. List prices were used for mitoxantrone, abiraterone and enzalutamide as directed by NICE, although commercial in-confidence patient-access schemes (PASs) are in place for abiraterone and enzalutamide. The confidential PAS was used for cabazitaxel. Sequential use of the advanced hormonal therapies (abiraterone and enzalutamide) does not usually occur in clinical practice in the UK. Hence, cabazitaxel could be used within two pathways of care: either when an advanced hormonal therapy was used pre-docetaxel, or when one was used post-docetaxel. The company believed that the former pathway was more likely to represent standard National Health Service (NHS) practice, and so their main comparison was between cabazitaxel and mitoxantrone, with effectiveness data from the TROPIC trial. Results of the company's updated cost-effectiveness analysis estimated a probabilistic incremental cost-effectiveness ratio (ICER) of £45,982 per quality-adjusted life-year (QALY) gained, which the committee considered to be the most plausible value for this comparison. Cabazitaxel was estimated to be both cheaper and more effective than abiraterone. Cabazitaxel was estimated to be cheaper but less effective than enzalutamide, resulting in an ICER of £212,038 per QALY gained for enzalutamide compared with cabazitaxel. The ERG noted that radium-223 is a valid comparator (for the indicated sub-group), and that it may be used in either of the two care pathways. Hence, its exclusion leads to uncertainty in the cost-effectiveness results. In addition, the company assumed that there would be no drug wastage when cabazitaxel was used, with cost-effectiveness results being sensitive to this assumption: modelling drug wastage increased the ICER comparing cabazitaxel with mitoxantrone to over £55,000 per QALY gained. The ERG updated the company's NMA and used a random effects model to perform a fully incremental analysis between cabazitaxel, abiraterone, enzalutamide and best supportive care using PASs for abiraterone and enzalutamide. Results showed that both cabazitaxel and abiraterone were extendedly dominated by the combination of best supportive care and enzalutamide. Preliminary guidance from the committee, which included wastage of cabazitaxel, did not recommend its use. In response, the company provided both a further discount to the confidential PAS for cabazitaxel and confirmation from NHS England that it is appropriate to supply and purchase cabazitaxel in pre-prepared intravenous-infusion bags, which would remove the cost of drug wastage. As a result, the committee recommended use of cabazitaxel as a treatment option in people with an Eastern Cooperative Oncology Group performance status of 0 or 1 whose disease had progressed during or after treatment with at least 225 mg/m2 of docetaxel, as long as it was provided at the discount agreed in the PAS and purchased in either pre-prepared intravenous-infusion bags or in vials at a reduced price to reflect the average per-patient drug wastage.

3. Innovative Oncology Care Models Improve End-Of-Life Quality, Reduce Utilization And Spending.

Authors
Murphy Colligan, Erin; Ewald, Erin; Ruiz, Sarah; Spafford, Michelle; Cross-Barnet, Caitlin; Parashuram, Shriram

Source
Health Affairs; Mar 2017; vol. 36 (no. 3); p. 433-440

Publication Date
Mar 2017

Publication Type(s)
Academic Journal

Database
HBE
Abstract

Three models that received Health Care Innovation Awards from the Centers for Medicare and Medicaid Services (CMS) aimed to reduce the cost and use of health care services and improve the quality of care for Medicare beneficiaries with cancer. Each emphasized a different principle: the oncology medical home, patient navigation, or palliative care. Comparing participants in each model who died during the study period to matched comparators, we found that the oncology medical home and patient navigation models were associated with decreased costs in the last ninety days of life ($3,346 and $5,824 per person, respectively) and fewer hospitalizations in the last thirty days of life (fifty-seven and forty per 1,000 people, respectively). The patient navigation model was also associated with fewer emergency department visits in the last thirty days of life and increased hospice enrollment in the last two weeks of life. These promising results can inform new initiatives for cancer patients, such as the CMS Oncology Care Model.


Authors
Zheng, Ying; Pan, Feng; Sorensen, Sonja

Source
PharmacoEconomics; Jan 2017; vol. 35 (no. 1); p. 15-24

Abstract
As the number of interventions available in a therapeutic area increases, the relevant decision questions in health technology assessment (HTA) expand to compare treatment sequences instead of discrete treatments and identify optimal sequences or position for a particular treatment in a sequence. The objective of this work was to review approaches used to model treatment sequences and provide practical guidance on conceptualizing whether and how to model sequences in health economic models. Economic models including treatment sequencing assessed by the National Institute for Health and Care Excellence were reviewed, as these assessments generally provide both policy relevance and comprehensive model detail. We identified 40 treatment-sequence models in the following disease areas: oncology (13), autoimmune (7), cardiovascular (6), neurology/mental health (4), infectious disease (2), diabetes (2), and other (6). Modeling techniques included discrete event simulation (6), individual state-transition (3), decision tree (3) and, most commonly, cohort state-transition with tracking states (28). In most cases, treatment sequencing had been incorporated to reflect either clinical practice or clinical trial design. In other cases, it was used to assess where in a treatment sequence a new treatment should be placed, or to evaluate the addition of more efficacious treatment options to a current treatment sequence. Important considerations for determining how to best model sequences include the number of treatment options, patient heterogeneity, key outcomes, and event risk (time-varying or constant). The biggest challenge is the scarcity of clinical data, as clinical trials do not commonly evaluate different treatment sequences.

5. Risk-stratified surveillance and cost effectiveness of follow-up after radical cystectomy in patients with muscle-invasive bladder cancer.

Authors
Kusaka, Ayumu; Hatakeyama, Shingo; Hosogoe, Shogo; Hamano, Itsuto; Iwamura, Hiromichi; Fujita, Naoki; Fukushi, Ken; Narita, Takuma; Hagiwara, Kazuhisa; Yamamoto, Hayato; Tobisawa, Yuri; Yoneyama, Tohru; Yoneyama, Takahiro; Hashimoto, Yasuhiro; Koie, Takuya; Ito, Hiroyuki; Yoshikawa, Kazuaki; Kawaguchi, Toshiaki; Ohyama, Chikara

Source
Oncotarget; Sep 2017; vol. 8 (no. 39); p. 65492-65505

Abstract
BACKGROUND The recurrence risk stratification and the cost effectiveness of oncological surveillance after radical cystectomy are not clear. We aimed to develop a risk stratification and a surveillance protocol with improved cost effectiveness after radical cystectomy. RESULTSOF 581 enrolled patients, 175 experienced disease recurrences. The pathology-based protocol presented significant differences in recurrence-free survival between normal- and high-risk patients, but the medical expense was high, especially in normal-risk (spT2Pn0) patients. Cox regression analysis identified six factors associated with recurrence-free survival. Risk score-based 5-year follow-up was significantly more cost effective than the pathology-based protocol. MATERIALS AND METHODS We retrospectively evaluated 581 patients with radical cystectomy for muscle-invasive bladder cancer at 4 hospitals. Patients with routine oncological follow-up were stratified into normal- and high-risk groups by a pathology-based protocol utilizing pT, pN, lymphovascular invasion, and histology. Cost effectiveness of the pathology-based protocol was evaluated and a risk-score-based protocol was developed to optimize cost effectiveness. Risk-scores were calculated by summing risk factors independently associated with recurrence-free survival. Patients were stratified by low-, intermediate-, and high-risk score. Estimated cost per one recurrence detection by the pathology and by risk-scores were compared. CONCLUSIONS Risk-score-stratified surveillance protocol has potential to reduce over-evaluation after radical cystectomy without adverse effects on medical cost.

Authors
Kearns, Benjamin; Pandor, Abdullah; Stevenson, Matt; Hamilton, Jean; Chambers, Duncan; Clowes, Mark; Graham, John; Kumar, M Satish

Source
PharmacoEconomics; Apr 2017; vol. 35 (no. 4); p. 415-424

Abstract
As part of its single technology appraisal (STA) process, the National Institute for Health and Care Excellence (NICE) invited the company that manufactures cabazitaxel (Jevtana®, Sanofi, UK) to submit evidence for the clinical and cost effectiveness of cabazitaxel for treatment of patients with metastatic hormone-relapsed prostate cancer (mHRPC) previously treated with a docetaxel-containing regimen. The School of Health and Related Research Technology Appraisal Group at the University of Sheffield was commissioned to act as the independent Evidence Review Group (ERG). The ERG produced a critical review of the evidence for the clinical and cost effectiveness of the technology based upon the company’s submission to NICE. Clinical evidence for cabazitaxel was derived from a multinational randomised open-label phase III trial (TROPIC) of cabazitaxel plus prednisone or prednisolone compared with mitoxantrone plus prednisone or prednisolone, which was assumed to represent best supportive care. The NICE final scope identified a further three comparators: abiraterone in combination with prednisone or prednisolone; enzalutamide; and radium-223 dichloride for the subgroup of people with bone metastasis only (no visceral metastasis). The company did not consider radium-223 dichloride to be a relevant comparator. Neither abiraterone nor enzalutamide has been directly compared in a trial with cabazitaxel. Instead, clinical evidence was synthesised within a network meta-analysis (NMA). Results from TROPIC showed that cabazitaxel was associated with a statistically significant improvement in both overall survival and progression-free survival compared with mitoxantrone. Results from a random-effects NMA, as conducted by the company and updated by the ERG, indicated that there was no statistically significant difference between the three active treatments for both overall survival and progression-free survival. Utility data were not collected as part of the TROPIC trial, and were instead taken from the company’s UK early access programme. Evidence on resource use came from the TROPIC trial, supplemented by both expert clinical opinion and a UK clinical audit. List prices were used for mitoxantrone, abiraterone and enzalutamide as directed by NICE, although commercial in-confidence patient-access schemes (PASs) are in place for abiraterone and enzalutamide. The confidential PAS was used for cabazitaxel. Sequential use of the advanced hormonal therapies (abiraterone and enzalutamide) does not usually occur in clinical practice in the UK. Hence, cabazitaxel could be used within two pathways of care: either when an advanced hormonal therapy was used pre-docetaxel, or when one was used post-docetaxel. The company believed that the former pathway was more likely to represent standard National Health Service (NHS) practice, and so their main comparison was between cabazitaxel and mitoxantrone, with effectiveness data from the TROPIC trial. Results of the company’s updated cost-effectiveness analysis estimated a probabilistic incremental cost-effectiveness ratio (ICER) of £45,982 per quality-adjusted life-year (QALY) gained, which the committee considered to be the most plausible value for this comparison. Cabazitaxel was estimated to be both cheaper and more effective than abiraterone. Cabazitaxel was estimated to be cheaper but less effective than enzalutamide, resulting in an ICER of £212,038 per QALY gained for enzalutamide compared with cabazitaxel. The ERG noted that radium-223 is a valid comparator (for the indicated sub-group), and that it may be used in either of the two care pathways. Hence, its exclusion leads to uncertainty in the cost-effectiveness results. In addition, the company assumed that there would be no drug wastage when cabazitaxel was used, with cost-effectiveness results being sensitive to this assumption: modelling drug wastage increased the ICER comparing cabazitaxel with mitoxantrone to over £55,000 per QALY gained. The ERG updated the company’s NMA and used a random effects model to perform a fully incremental analysis between cabazitaxel, abiraterone, enzalutamide and best supportive care using PASs for abiraterone and enzalutamide. Results showed that both cabazitaxel and abiraterone were extensively dominated by the combination of best supportive care and enzalutamide. Preliminary guidance from the committee, which included wastage of cabazitaxel, did not recommend its use. In response, the company provided both a further discount to the confidential PAS for cabazitaxel and confirmation from NHS England that it is appropriate to supply and purchase cabazitaxel in pre-prepared intravenous-infusion bags, which would remove the cost of drug wastage. As a result, the committee recommended use of cabazitaxel as a treatment option in people with an Eastern Cooperative Oncology Group performance status of 0 or 1 whose disease had progressed during or after treatment with at least 225 mg/m2 of docetaxel, as long as it was provided at the discount agreed in the PAS and purchased in either pre-prepared intravenous-infusion bags or in vials at a reduced price to reflect the average per-patient drug wastage.

7. Making Molecular Imaging a Clinical Tool for Precision Oncology: A Review.

Authors
Mankoff, David A; Farwell, Michael D; Clark, Amy S; Pryma, Daniel A

Source
JAMA oncology; May 2017; vol. 3 (no. 5); p. 695-701
Importance Individualized cancer treatment, tailored to a particular patient and the tumor's biological features (precision oncology), requires a detailed knowledge of tumor biology. Biological characterization is typically performed on biopsy material, but this approach can present challenges for widespread and/or heterogeneous disease and for performing serial assays to infer changes in response to therapy. Molecular imaging is a complementary approach that provides noninvasive and quantitative measures of the in vivo biology of the full disease burden and is well suited to serial assay.

Observations Molecular imaging can provide unique information to guide precision oncology that includes measuring the regional expression of therapeutic targets, measuring drug pharmacokinetics, measuring therapy pharmacodynamics, and providing a marker of therapeutic efficacy that is highly indicative of outcome. Thus far, most trials of novel molecular imaging in oncology have been small, single-center trials. Only a few methods have progressed to multicenter trials and even fewer have become part of clinical practice.

Conclusions and Relevance Molecular imaging holds great promise for precision oncology, complementing tissue-based markers to guide more effective, less toxic, and more cost-effective cancer treatments. Beyond logistical and technical challenges, moving new imaging tests from the laboratory to the clinic requires a compelling use case that will benefit patients and/or improve cost-effectiveness, and it requires the collaboration of imagers, oncologists, and industry to reach its true clinical potential.

8. Rivaroxaban: An Affordable and Effective Alternative in Cancer-Related Thrombosis?

Authors
Xavier, Flávia Dias; Hoff, Paulo Marcelo Gehm; Braghiroli, Maria Igniez; Paterlini, Ana Carolina Carvalho Rocha; Souza, Karla Teixeira; Faria, Luiza Díb Batista Bugiato; Ferreira, Fernando Sergio Blumm; Machado, Karime Kallí; Fernandes, Gustavo Dos Santos

Source
Journal of global oncology; Feb 2017; vol. 3 (no. 1); p. 15-22

Abstract
BACKGROUND Venous thromboembolic events (VTEs) are common and potentially fatal complications in cancer patients, and they are responsible for the second most common cause of death. Low molecular weight heparin (LMWH) is the gold-standard treatment, but the costs involved limit its use, especially in developing countries. Recently, the oral anticoagulant rivaroxaban, which directly inhibits factor Xa, was approved for VTE treatment.

METHODS We conducted a retrospective analysis from January 2009 to February 2014 with patients who had cancer and VTE who were receiving rivaroxaban. We compared the efficacy, safety, and cost of rivaroxaban and low molecular weight heparin (LMWH) alone or followed by vitamin K antagonists.

RESULTS Forty-one patients were identified, with a median age of 62.5 years. The most frequent tumor histology was adenocarcinoma (78%), which was most often found in the colon (26.8%). Most participants had advanced disease and an implanted central venous catheter. Patients’ VTE risk-assessment scores were low (12.5%), intermediate (50%), and high (35.5%). Pulmonary thromboembolism was reported in 41.4% of patients, but inferior limb thrombosis was reported only in 14.6%; 43.9% of patients received enoxaparin before starting rivaroxaban. Rivaroxaban was used for a median time of 5.5 months. Nonmajor bleeding was reported in 12.2% of patients, and rethrombosis was reported in 12.2%. In our study, rivaroxaban was as safe and effective as enoxaparin/vitamin K antagonists (P = .54 and P = .25, respectively) or LMWH (P = .46 and P = .29, respectively).

CONCLUSION Although our study was a retrospective analysis, our results suggest that in this cohort of oncologic patients, rivaroxaban was safe and effective. Its oral route and lower cost make it an attractive alternative to LMWH, improving management of patients with cancer in low-income countries. Additional studies are necessary to confirm our data.

9. The evaluation of enhanced feedback interventions to reduce unnecessary blood transfusions (AFFINITIE): protocol for two linked cluster randomised factorial controlled trials.

Authors
Hartley, Suzanne; Foy, Robbie; Walwyn, Rebecca E A; Cicero, Robert; Farrin, Amanda J; Francis, Jill J; Lorencatto, Fabiana; Gould, Natalie J; Grant-Casey, John; Grimshaw, Jeremy M; Glidewell, Liz; Michie, Susan; Morris, Stephen; Stanworth, Simon J; AFFINITIE programme

Source
Implementation science : IS; Jul 2017; vol. 12 (no. 1); p. 84

Abstract
BACKGROUND Haematology and Oncology Cost Savings LIBGUIDES nov 17

Page 6 of 11
Abstract

Blood for transfusion is a frequently used clinical intervention, and is also a costly and limited resource with risks. Many transfusions are given to stable and non-bleeding patients despite no clear evidence of benefit from clinical studies. Audit and feedback (A&F) is widely used to improve the quality of healthcare, including appropriate use of blood. However, its effects are often inconsistent, indicating the need for coordinated research including more head-to-head trials comparing different ways of delivering feedback. A programmatic series of research projects, termed the 'Audit and Feedback Interventions to Increase evidence-based Transfusion practice' (AFFINITIE) programme, aims to test different ways of developing and delivering feedback within an existing national audit structure.

METHODS

The evaluation will comprise two linked 2×2 factorial, cross-sectional cluster-randomised controlled trials. Each trial will estimate the effects of two feedback interventions, 'enhanced content' and 'enhanced follow-on support', designed in earlier stages of the AFFINITIE programme, compared to current practice. The interventions will be embedded within two rounds of the UK National Comparative Audit of Blood Transfusion (NCABT) focusing on patient blood management in surgery and use of blood transfusions in patients with haematological malignancies. The unit of randomisation will be National Health Service (NHS) trust or health board. Clusters providing care relevant to the audit topics will be randomised following each baseline audit (separately for each trial), with stratification for size (volume of blood transfusions) and region (Regional Transfusion Committee). The primary outcome for each topic will be the proportion of patients receiving a transfusion coded as unnecessary. For each audit topic a linked, mixed-method fidelity assessment and cost-effectiveness analysis will be conducted in parallel to the trial.

DISCUSSION

AFFINITIE involves a series of studies to explore how A&F may be refined to change practice including two cluster randomised trials linked to national audits of transfusion practice. The methodology represents a step-wise increment in study design to more fully evaluate the effects of two enhanced feedback interventions on patient- and trust-level clinical, cost, safety and process outcomes.

TRIAL REGISTRATION


Authors

Gurevich-Shapiro, Anna; Tzadok, Sharon; Rosenberg, Alina; Inbal, Aida; Bar-Natan, Michal; Wolach, Ofir; Raanani, Pia

Source

Acta haematologica; 2017; vol. 137 (no. 4); p. 183-190

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2017

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Controlled Clinical Trial Journal Article

PubMedID

28419992

Database

Medline

Abstract

Refactoriness to platelet transfusion, prevalent among 15-20% of hemato-oncological patients, is associated with multitransfusions and inferior outcomes. We evaluated the effectiveness of extended slow-dose transfusion (ESDT) in increasing platelet increments in multitransfused patients. Patients treated after the implementation of ESDT were compared with historical controls treated with standard single-donor platelet (SDP) transfusions. Cohorts of early and late recipients were assembled for comparison, i.e. the 8th or 9th and 11th platelet unit per patient, respectively. Patients in the ESDT group received transfusions equal to half an SDP unit, administered over 4 h. Effectiveness was defined as a higher corrected count increment (CCI) at 1, 12, and 24 h after transfusion.

RESULTS

The 24-h-posttransfusion increment was available for 20 ESDT patients and 7 standard patients in the late-recipients cohort. The CCI was significantly higher in the ESDT group (p = 0.042). ABO compatibility improved the CCI (p = 0.01). CONCLUSION

ESDT demonstrated slightly higher increments at 24 h after transfusion in late recipients, suggesting this could be a cost-effective approach for the treatment of thrombocytopenic multitransfused hemato-oncological patients.

11. Rehabilitation and exercise oncology program: translating research into a model of care.

Authors

Dalzell, M A; Smirnow, N; Sateren, W; Sinharaphone, A; Ibrahim, M; Mastroianni, L; Vales Zambrano, L D; O’Brien, S

Source

Current oncology (Toronto, Ont.); Jun 2017; vol. 24 (no. 3); p. e191

Publication Date

Jun 2017

Publication Type(s)

Journal Article

PubMedID

28680286

Database

Medline

Available at Current Oncology from Europe PubMed Central - Open Access
INTRODUCTION
The Rehabilitation and Exercise Oncology model of care (ActivOnco) was established to optimize cancer survivorship through exercise prescription and active lifestyle promotion, providing a transition of care from hospital to community. Patients having any cancer diagnosis, stage of disease, and treatment were eligible for evaluation and exercise prescription upon deterioration of performance status. The team of professionals included hospital-based physiotherapists proactively screening for rehabilitation needs, loss of functional independence, and exercise eligibility, plus exercise specialists in a community-based Wellness Centre to provide follow-up or direct access for post-treatment or non-complex patients.

METHODS
From January 2011 to December 2015, the hospital team assessed 1635 patients representing all major cancer sites, and the Wellness Centre team evaluated and prescribed exercise for 1066 participants. Primary interventions provided were education about fatigue management, physical activity promotion, exercise prescription, fracture risk reduction, referral to specialized follow-up services (for example, occupational therapy, lymphedema clinic), and coordination for mobility aids and paratransit services.

RESULTS AND CONCLUSIONS
Implementation of the ActivOnco model of care showed that exercise alone is not a panacea for all functional deterioration associated with the cancer trajectory and its treatment. However, screening to identify rehabilitation needs combined with exercise prescription can effectively improve the quality of survivorship in cancer patients. Program developments are limited by the cost of human resources, lack of hospital-based physical resources, and lack of public funding, all of which significantly limit the scope and development of appropriate services.


Authors: Dzimitrowicz, Hannah; Mougalian, Sarah; Storms, Sherri; Hurd, Sandra; Chagpar, Anees B; Killelea, Brigid K; Horowitz, Nina R; Lannin, Donald R; Harigopal, Malini; Hofstatter, Erin; DiGiovanna, Michael P; Adelson, Kerin B; Silber, Andrea; Abu-Khalaf, Maysa; Chung, Gina; Zaheer, Wajih; Abdelghany, Osama; Hatzis, Christos; Puszta, Lajos; Sanft, Tara B

Source: Journal of oncology practice; Oct 2017; p. JOP2017022731

PURPOSE
The 21-gene recurrence score (RS) assay is used to help formulate adjuvant chemotherapy recommendations for patients with estrogen receptor-positive, early-stage breast cancer. Most frequently, medical oncologists order RS after surgery. Results take an additional 2 weeks to return, which can delay decision making. We conducted a prospective quality-improvement project to assess the impact of early guideline-directed RS ordering by surgeons before the first visit with a medical oncologist on adjuvant therapy decision making.

METHODS
Surgical oncologists ordered RS testing following National Comprehensive Cancer Network guidelines at time of diagnosis or at time of surgery between July 1, 2015 and December 31, 2015. We measured the testing rate of patients eligible for RS, time to chemotherapy decisions, rates of chemotherapy use, accrual to RS-based clinical trials, cost, and physician acceptance of the policy and compared the results to patients who met eligibility criteria for early guideline-directed testing during the 6 months before the project.

RESULTS
Ninety patients met eligibility criteria during the testing period. RS was ordered for 91% of patients in the early testing group compared with 76% of historical controls ($P < .001$). Median time to chemotherapy decision was significantly shorter in the early testing group (20 days; 95% CI, 17 to 23 days) compared with historical controls (32 days; 95% CI, 29 to 35 days; $P < .001$). There were no significant differences in time to chemotherapy initiation, chemotherapy use, RS-based trial enrollment, or calculated costs between the groups.

CONCLUSION
Early guideline-directed RS testing in selected patients is an effective way to shorten time to treatment decisions.

13. A supportive care in cancer unit reduces costs and hospitalizations for transfusions in a comprehensive cancer center.

Authors: Ripamonti, Carla Ida; Molani, Pietro; Desti, Cinzia; Boscagli, Giacomo; Ravagnani, Fernando; Arienti, Flavio; Di Cristo, Clementina

Source: Tumori; Sep 2017; vol. 103 (no. 5); p. 449-456

PURPOSE
A supportive care in cancer unit reduces costs and hospitalizations for transfusions in a comprehensive cancer center.
Abstract

PURPOSE Among patients with solid or hematologic malignancies undergoing oncologic therapies, blood product transfusions (BPT) are a relevant reason for planned/unplanned hospitalizations, as well as a possible cause of delay in administration of the oncologic therapies. Furthermore, they create additional costs for the healthcare system (HCS). The aim of this study was to compare the costs of performing BPT (erythrocytes and platelets) in medical units/wards to the costs derived from the administration of BPT in a dedicated outpatient supportive care in cancer unit (SCCU).

METHODS Costs were analyzed from June 3, 2009 (when the SCCU started), until December 2013. Four inpatient oncologic units (bone marrow transplantation, radiotherapy, medical oncology I and II) were compared to the SCCU. Data regarding the transfusions performed by the SCCU of the patients who were previously hospitalized for transfusions were extracted, checked, and analyzed through a cross-check on the tax codes. Therefore, patients were considered suitable for the analysis if they had received BPT in the SCCU after a previous hospitalization for transfusion in one of the 4 units/wards. The average daily cost deriving from blood product units and from the hospitalization in each ward (irrespective of pharmaceutical expenses) was compared with the average daily cost deriving from blood product units and from the management of patients in the SCCU.

RESULTS We analyzed 227 patients (112 female) with a mean age of 60 years (range 20-90) with hematologic malignancies in 79% of cases. The number of transfusions performed by the SCCU has grown constantly and consistently over the years, reaching 1,402 transfusions in 2013, thus exceeding the other considered units. The total savings for the HCS was €282,204.71, €151,182.85 in 2013 only. We saved €124,319.26 for each patient transfused at the SCCU.

CONCLUSION A dedicated outpatient SCCU, aimed at monitoring and treating cancer therapy-related toxicities and comorbidities and in which it is also possible to perform BPT promptly and effectively, reduces the number of hospitalizations and provides an economical benefit for HCS.


Authors

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Source

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Abstract

BACKGROUND New immuno-oncology (I-O) therapies that harness the immune system to fight cancer call for a re-examination of the traditional parametric techniques used to model survival from clinical trial data. More flexible approaches are needed to capture the characteristic I-O pattern of delayed treatment effects and, for a subset of patients, the plateau of long-term survival.

OBJECTIVES Using a systematic approach to data management and analysis, the study assessed the applicability of traditional and flexible approaches and, as a test case of flexible methods, investigated the suitability of restricted cubic splines (RCS) to model progression-free survival (PFS) in I-O therapy.

METHODS The goodness of fit of each survival function was tested on data from the CheckMate 067 trial of monotherapy versus combination therapy (nivolumab/ipilimumab) in metastatic melanoma using visual inspection and statistical tests. Extrapolations were validated using long-term data for ipilimumab.

RESULTS Modelled PFS estimates using traditional methods did not provide a good fit to the Kaplan-Meier (K-M) curve. RCS estimates fit the K-M curves well, particularly for the plateau phase. RCS with six knots provided the best overall fit, but RCS with one knot performed best at the plateau phase and was preferred on the grounds of parsimony.

CONCLUSION RCS models represent a valuable addition to the range of flexible approaches available to model survival when assessing the effectiveness and cost-effectiveness of I-O therapy. A systematic approach to data analysis is recommended to compare the suitability of different approaches for different diseases and treatment regimens.

15. Rational therapeutic choice for older patients with lymphoma.

Authors

Bron, Dominique; Soubeyran, Pierre; EHA SWG on 'Aging, Hematology'

Source

Current opinion in oncology; Sep 2017; vol. 29 (no. 5); p. 322-327

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PURPOSE OF REVIEW
The choice for an optimal treatment in older lymphoma patients is a real challenge for hemato-oncologists. They have to treat a potentially curative lymphoma, and concomitantly protect their patients from unacceptable toxicities. Some recommendations are provided for the major subtypes of lymphomas including the antitumoral treatment and primarily the optimal supportive care.

RECENT FINDINGS
All the recent literature data converge to say that the approach of an older patient with a malignant hemopathy is a multistep procedure. This process comprises the appraisal of life expectancy of the patient with or without the disease, the prognostic factors of the tumor, the functional, physiological and cognitive functions evaluation, the socio-economical environment and the patient's expectancy in terms of quality of life. Major progresses have been achieved in the management of diffuse large B cell lymphoma and mantle cell lymphoma in patients up to 80 and above 80 years old.

SUMMARY
With all these information in hands, the hematologist will decide if the treatment's objective is the standard treatment with optimal supportive care (fit patients), tailor-made adapted chemotherapy (unfit patients) or preservation of quality of life (frail patients).

Authors
Savage, P
Source
Clinical oncology (Royal College of Radiologists (Great Britain)); Sep 2017; vol. 29 (no. 9); p. 547-549
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17. Human papillomavirus vaccination and risk of autoimmune diseases: A large cohort study of over 2 million young girls in France.
Authors
Miranda, Sara; Chaignot, Christophe; Collin, Cédric; Dray-Spira, Rosemary; Weill, Alain; Zureik, Mahmoud
Source
Vaccine; Aug 2017; vol. 35 (no. 36); p. 4761-4768
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18. Innovative haematological parameters for early diagnosis of sepsis in adult patients admitted in intensive care unit.
Authors
Buoro, Sabrina; Manenti, Barbara; Seghezzi, Michela; Dominoni, Paola; Barbui, Tiziano; Ghirardi, Arianna; Carobbio, Alessandra; Marchesi, Gianmariano; Riva, Ivano; Nasi, Alessandra; Ottomano, Cosimo; Lippi, Giuseppe
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Abstract
BACKGROUND Whether human papillomavirus (HPV) vaccination could induce or trigger autoimmune diseases (AID) has been questioned, and potentially contributes to low immunization coverage in France. This study evaluated the association between HPV vaccination and the risk of AID using routinely collected data sources.

METHODS All girls aged 13-16 years between 2008 and 2012, covered by the general health insurance scheme and without history of HPV vaccination or AID, were included and followed using French nationwide databases. Fourteen neurological, rheumatological, haematological, gastrointestinal or endocrine AID, were identified from ICD-10 codes allocated to hospital stays and long-term illnesses or by marker drugs. Their incidence was compared between girls exposed and non-exposed to HPV vaccination, using a Cox model adjusted for inclusion year, geographic area, socio-economic indicators, healthcare use level and other immunizations.

RESULTS Among 2,252,716 girls, 37% received HPV vaccine and 4,096 AID occurred during a mean follow-up time of 33 months. The incidence of AID was not increased after exposure to HPV vaccination, except for Guillain-Barré syndrome (GBS) (incidence rate of 1.4 among exposed [20 cases] versus 0.4 per 100,000 PY among unexposed [23 cases]; adjusted HR: 3.78 [1.79-7.98]). This association persisted across numerous sensitivity analyses and was particularly marked in the first months following vaccination. Under the hypothesis of a causal relationship, this would result in 1-2 GBS cases attributable to HPV vaccine per 100,000 girls vaccinated.

CONCLUSIONS Our study provides reassuring results regarding the risk of AID after HPV vaccination, but an apparently increased risk of GBS was detected. Further studies are warranted to confirm this finding.
AIMS This study was aimed to investigate the role of erythrocyte, platelet and reticulocyte (RET) parameters, measured by new haematological analyser Sysmex XN and C reactive protein (CRP), for early diagnosis of sepsis during intensive care unit (ICU) stay.

METHODS The study population consisted of 62 ICU patients, 21 of whom developed sepsis during ICU stay and 41 who did not. The performance for early diagnosing of sepsis was calculated as area under the curve (AUC) of receiver operating characteristics curves analysis.

RESULTS Compared with CRP (AUC 0.81), immature platelet fraction (IPF) (AUC 0.82) showed comparable efficiency for identifying the onset of sepsis. The association with the risk of developing sepsis during ICU stay was also assessed. One day before the onset of sepsis, a decreased of RET% was significantly associated with the risk of developing sepsis (OR = 0.35, 95% CI 0.14 to 0.87), whereas an increased of IPF absolute value (IPF#) was significantly associated with the risk of developing sepsis (OR = 1.13, 95% CI 1.03 to 1.24) 2 days before the onset of sepsis. The value of CRP was not predictive of sepsis at either time points.

CONCLUSIONS IPF# and RET% may provide valuable clinical information for predicting the risk of developing sepsis, thus allowing early management of patients before the onset of clinically evident systemic infections.