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Abraxane® versus Taxol® for patients with advanced breast cancer: A prospective time and motion analysis from a Chinese health care perspective

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Abstract

Background: Abraxane® and Taxol® are both effective drugs for the treatment of advanced stage breast cancer. However, each agent possesses unique drug delivery characteristics with the former not requiring premedication and having a considerably shorter recommended infusion time (i.e. 30 min vs. 2–4 h). To measure the overall efficiency and cost-saving potential associated with Abraxane® relative to Taxol®, a time and motion study was undertaken in breast cancer patients treated in China.

Methods: Baseline patient data collection included age, disease stage, number and sites of metastatic disease, and performance status. Time and resource use data were then collected from breast patients being treated with Abraxane® ($n = 12$) or Taxol® ($n = 15$) in one of three cancer clinics located in Jiangsu, Shanghai, and Beijing. Resource use and time impact on clinical staff were quantified using unit cost estimates. This included costs for drug preparation, administration, materials and supplies, premedication, patient chair time, labor costs, and all acute adverse drug reactions. Outcomes were presented as a mean total time and cost for delivering a dose of Abraxane® or Taxol® and were compared using parametric and non-parametric statistical tests where appropriate. All costs were reported in US dollars (US$1 = 6.1 RMB, as of January 2014).

Results: Patients were comparable with respect to mean age, number of metastatic sites, and performance status. Approximately 9 of 12 (75%) patients received Abraxane® as on a weekly schedule (vs. every 3 weeks) compared to 6 of 15 (40%) with Taxol®. There were 5 (33.3%) acute adverse drug reactions with Taxol®, 3 of which required a physician visit and the initiation of supportive interventions. In contrast, there was only one minor event with Abraxane® (8.3%), which was easily managed with a temporary stoppage of the infusion. From the time and motion study, the mean total time for Abraxane® and Taxol® delivery (preparation, administration, premedication, total chair time, and adverse effects management) was 84 and 282 min respectively ($p < 0.001$), with the associated costs being US$59 and US$254 respectively per dose ($p < 0.001$).

Conclusion: To our knowledge, this is first such study in breast cancer patients to be undertaken in China. Abraxane® was associated with fewer acute adverse drug reactions and significant reductions in health care resources, physician/nurse time and overall drug delivery costs compared to Taxol®.

Keywords

Abraxane®, paclitaxel, metastatic breast cancer, resource use, cost analysis

Background

Breast cancer is the most common invasive cancer form in women in both the developed and less developed world, with more than one new million cases and 508,000 deaths occurring worldwide annually.[1] Advanced breast cancer in stage IV (i.e. metastatic) is

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an incurable disease, where median survival can be expected to be 3 to 4 years when access to effective drugs is available.[2] As a result, a major focus of chemotherapy in metastatic breast cancer (MBC) is for the palliation of disease-related symptoms and the prolongation of survival. The optimal use of cytotoxic agents in the metastatic setting presents many challenges to the medical oncologist. Factors that have to be considered include patient age, performance status, the presence of life threatening metastases, the previous chemotherapy used in the adjuvant setting, and the duration of relapse-free survival.[3]

Chemotherapy with the taxane class of drugs (paclitaxel or docetaxel) is commonly used as first-line therapy for advanced breast cancer in many countries around the world. They are effective in prolonging survival, but are also associated with serious adverse events, such as neutropenia, anemia, neuropathy, and diarrhea.[4,5] These adverse events may be dose-limiting in all groups of breast cancer patients (not only the frail and elderly) and hence can impact the antitumour effects.[5,6] Furthermore, both paclitaxel and docetaxel require premedication, special infusion sets and have a substantial "chair time" for drug administration. In the case of paclitaxel, the recommended infusion time is 2 to 4 h.[5] Overall, these characteristics translate to increased costs for drug delivery and an excessive burden on the patient.[7,8]

In order to improve the safety and overall efficacy of paclitaxel, an albumin-bound formulation was developed. Abraxane® has been approved for the treatment of patients with MBC in the United States, Europe, Australia, and many Asian countries including China based on the results of randomized trials.[9–11] The initial approval in MBC was from the findings of a large randomized comparative trial. In that study, 454 patients, 186 of whom had not received prior therapy for metastatic disease, were randomized to receive Abraxane® (260 mg/m^2 over 30 min without standard premedication or special infusion sets) or paclitaxel (175 mg/m^2 over 3 h) every 3 weeks until disease progression or the development of severe toxicity.[9] The major study endpoints were overall response rate, time to progression (TTP), overall survival and safety. Abraxane® was statistically superior to paclitaxel in terms of objective tumour (33% vs. 19%; $p = 0.001$) and TTP (23 vs. 16.9 weeks; $p = 0.006$). When the efficacy analysis focused on the first-line treatment setting, the overall response rate (42% vs. 27%; $p = 0.029$) and TTP (24 vs. 19.7 weeks; $p =$ NS) were also in favour of Abraxane®. There was no difference in overall survival. With respect to safety, patients randomized to the Abraxane® arm had a lower incidence of grade IV neutropenia (9% vs. 22%; $p = 0.046$) with hypersensitivity reactions being less than 1%. However, grade III sensory neuropathy was increased with Abraxane® (10% vs. 2% with paclitaxel).[9]

Weekly schedules of Abraxane® and paclitaxel were also evaluated in a randomized trial that reported the interim results in abstract form at the 2012 meeting of the American Society of Clinical oncology.[12] In contrast to the initial trial which compared every 3-week schedule, there was no significant difference in progression free survival. In addition, >grade II sensory neuropathy (48% vs. 37%) and >grade III hematologic toxicity (49% vs. 12%) was higher with weekly Abraxane®.[12]

China is the world's most populous country with approximately 1.4 billion people as of January 2014.[13] Cancer is a major public health concern in China with the age-standardized incidence rate being approximately 339 per 100,000 people.[14] With respect to cancer-related death, the age standardized mortality is approximately 116 per 100,000 population.[15] The most common cause of cancer death for Chinese women is breast cancer, while malignancy of the lung, predominates in men.[13,14] Paclitaxel, both generic formulations and brand (Taxol®) have been available in China for over 10 years. Abraxane® is the most recent taxane to be approved for clinical use for MBC in China. Paclitaxel and Abraxane® are currently being administered on a weekly dosage regimen (e.g. weekly 3 out of 4 weeks) or every 3 weeks.

Given the availability of Abraxane® as an alternative to Taxol®, it would be of interest to Chinese government and private payers as well as hospital pharmacy and therapeutics committees to quantify the potential cost savings associated with Abraxane®. In this study, a prospective time and motion analysis was undertaken in three cancer centers to quantity health care resource use in terms of personnel, supplies and infusion chair time in breast cancer patients who received Abraxane® or Taxol® for the treatment of their disease.

Methods

Patients

This was a prospective time and motion study consisting of patients with MBC who were receiving Abraxane® or Taxol® (brand only) for the management of their disease. All patients were receiving treatment in one of three cancer clinics located in Jiangsu, Shanghai and Beijing, China. To be entered into the study, patients must have been receiving Abraxane® or Taxol® for the treatment of MBC as part of routine clinical practice and according to institutional administration guidelines. Patients were excluded if they were being treated with either drug as part of a clinical trial. To ensure that patients were receiving Abraxane® or

Taxol® under a "real world" setting, randomization was not employed in this study. The final protocol was approved by the Ethics Review board of each participating institution.

Data collection

For eligible patients, baseline data collection consisted of patient demographics, disease characteristics, site of metastases and Eastern Cooperative Oncology Group (ECOG) performance status. Data related to the administration of the Abraxane® or Taxol® consisted of cycle number, dosing schedule (weekly vs. every 3 weeks), dose in mg, use of concomitant targeted anticancer agents, premedication, and special infusion sets.

A time and motion study was undertaken at the three practice sites to measure overall time and health care resource use for the delivery of Abraxane® or Taxol®. Resource use data collection included time, personnel, materials (e.g. infusion bags, tubing), and supplies to prepare and administer the drug as well as all premedication. In addition, patient chair time to receive Abraxane® or Taxol® was collected. The relevant personnel for drug preparation and administration included both senior and junior pharmacists (the latter prepare chemotherapy) and nurses. Details of the relevant time measurements were as follows: time to prepare a dose, pharmacist's/nurse's time to check the final dose, nurse's time to prepare the IV infusion and total patient chair time to receive the IV infusion. All acute toxicities that developed during and just following the administration of Abraxane® or Taxol® were also recorded. All of the above data were collected using a standardized data collection form and used to calculate the total cost for administering a dose of Abraxane® or Taxol®. Unit costs for the individual health care resources were obtained from the Cancer Hospital of Fu Dan University and from the Beijing Municipal Commission of Development and Reform.[16] All costs were converted into US dollars using local exchange rates (US$1 = 6.1 RMB, as of January 2014).

Sample size and statistical considerations

Time and motion as well as resource use data were collected from 27 patients; 12 and 15 receiving Abraxane® or Taxol® respectively. With a sample of at least 12 patients per group, using an alfa of 0.05 and assuming a standard deviation of 50 and 80 min respectively, the study had a 90% power to detect a 50% reduction in the total time for drug delivery between Abraxane® and Taxol®. All data were initially presented descriptively as means, medians, or proportions with appropriate measures of variance. The Wilcoxon rank-sum test was used to compare total time and cost for drug delivery between drugs. All of the statistical analyses were performed using Stata, release 11.0 (Stata Corp., College Station, TX, USA).

Results

Over a 3-month period, 27 patients were enrolled into the study, 12 and 15 who received Abraxane® or Taxol®, respectively. Abraxane® was administered on a weekly schedule in 9 of 12 patients, with the remainder receiving the drug every 3 weeks. In the case of Taxol®, 6 and 9 patients were treated on a weekly and every 3-week regimen, respectively (Table 1). Patients were comparable with respect to age, disease stage, presence of multiple sites of metastases, and the limited use of targeted anticancer therapies (Table 1).

Table 1. Demographic and clinical characteristics of breast cancer patients receiving Abraxane® or Taxol®.

Parameter (range)	Abraxane® ($n = 12$)	Taxol® ($n = 15$)
Mean age	48 (32 to 60)	49 (32 to 66)
Treatment center		
Fu Dan Cancer Hospital	25%	75%
Chinese Academy of Medical Science	66.7%	25%
Jiangsu Provincial Cancer Hospital	8.3%	0.0%
Dosing schedule		
Weekly	75%	40%
Every 3 weeks	25%	60%
Median dose delivered		
Weekly schedule	200 mg (185 to 200)	120 mg (120 to 240)
q3wk schedule	400 mg (200 to 400)	240 mg (120 to 240)
Median cycle number	1 (1 to 3)	2 (1 to 8)
Disease stage		
Metastatic	92%	93%
Locally advanced	8%	7%
Metastatic sites		
Liver only	25%	0.0%
Lung only	8%	40%
Lymph nodes only	8%	13%
multiple	59%	47%
ECOG PS		
Zero	25%	47%
One	67%	53%
Two	8%	0.0%
Targeted agent added	8%	0.0%

ECOG PS: Eastern Cooperative Group performance status.

However, differences were noted in sites of metastatic disease and patient performance status. There were more patients in the Taxol® group who had a performance status of zero (47% vs. 25%).

Dose preparation and administration data were then collected from each group of patients. Minor differences were noted in who prepared and who checked the taxane doses between the two groups (Table 2). However, in all cases, the final dose was administered by the oncology nurse. The Taxol® product monograph recommends that all patients receive premedication consisting of oral dexamethasone, IV diphenhydramine, and IV ranitidine.[17] In contrast, Abraxane® does not require premedication. Consistent with the monograph, all patients in the Taxol® group received premedication consisting of dexamethasone, antihistamines, and IV ranitidine. In addition, 9 of 15 patients also received a 5HT3 antiemetic (Table 2). Contrary to recommendations of the product monograph, 7 of 12 Abraxane® patients received premedication. This consisted of oral dexamethasone (4 patients) and an IV 5HT3 antiemetic (3 patients). All of the premedication and supplies were quantified and included in the economic analysis.

The development of acute adverse reactions during the respective infusions was also monitored. Despite receiving the recommended premedication, 5 of 15 Taxol® patients (33%) developed an acute infusion reaction, 3 of which required a temporary stoppage of the infusion, a physician visit and the initiation of supportive interventions. In contrast, there was only one minor event with Abraxane® (8.3%), which was easily managed with a temporary stoppage of the infusion. From the current study, this corresponded to a fivefold increase in the risk of acute adverse events with Taxol® (odds ratio = 5.6; $p = 0.12$), despite the use of recommended prophylaxis.

The time requirement from health care staff for dose preparation and administration was then quantified (Table 2). The mean time for drug preparation was higher with Abraxane® than with Taxol® (27 vs 10.5 min). However, the mean drug infusion time was

Table 2. Resource use and time impact on clinical staff and on the patient.

Parameter (range)	Abraxane® ($n = 12$)	Taxol® ($n = 15$)
Dose prepared by:		
Junior pharmacist	42%	50%
Senior pharmacist	42%	50%
Nurse	16%	0.0%
Dose checked by:		
Nurse	50%	60%
Senior pharmacist	50%	7%
Junior pharmacist	0.0%	33%
Dose given by nurse	100%	100%
Premedication given	7 of 12 (58%)[a]	15 of 15 (100%)
Acute adverse drug reaction reported	1 of 12 (8%)	5 of 15 (33%)
Impact of adverse drug reaction		
Temporary stop of infusion	1 of 12	3 of 15
Supportive care intervention	0	3 of 15
Physician visit	0	3 of 15
Time and motion outcomes (mean)		
Dose preparation time	27 min (10 to 40)	10.5 min (3 to 30)
Dose checking time	7.2 min (2 to 10)	6.7 min (3 to 10)
Time to prepare the IV line	6.7 min (1 to 20)	4.0 min (1 to 10)
Time for drug infusion	19.3 min (10 to 32)	229 min (100 to 370)
Mean time before the administration chair became available for next patient	23.3 min (10 to 30)	31 min (10 to 60)
Total time for drug delivery (95%CI)[b]	83.4 min (75 to 92)	281 min (253 to 310)

[a]Four patients received oral dexamethasone and three patients received a 5HT3 antiemetic.
[b]Consists of all the time components required to deliver a dose to the patient and then make the infusion chair available for the next patient.

Table 3. Cost comparison for drug delivery between Abraxane® and Taxol®.

Parameter	Abraxane® ($n = 12$)	Taxol® ($n = 15$)
Drug preparation and administration[a]	$44.02	$224.90
Premedication	$14.55	$29.24
Total cost per dose (US$) (95%CI)[b]	$58.57 ($55 to $63)	$254.14 ($232 to $276)

[a]Consists of materials, personnel, and chair time.
[b]Final numbers may not add to exact estimates because of rounding errors.

approximately 210 min longer with Taxol® ($p < 0.01$). When the mean time required for overall drug delivery (which includes both drug preparation and infusion) was quantified, patients receiving Abraxane® required a mean of 197 fewer minutes that with Taxol® (Table 2).

Health care resource use, personnel and chair time associated with each taxane dose was then combined with the associated unit costs. There was a significant reduction in the cost for drug preparation and administration in patients treated with Abraxane® (US$44 vs. US$225; $p < 0.01$). In addition, there was also a 50% reduction in the cost of premedication with Abraxane® (Table 3). When all of the cost components were combined, the total mean cost for delivering a dose Abraxane® and Taxol® (not including the drug acquisition cost) was US$58.57 and US$254.14, respectively ($p < 0.01$). Over one full cycle of weekly therapy (i.e. 3 weekly doses, given 3 out of 4 week), the total cost savings for drug delivery would be substantial with Abraxane® (US$175.71 vs. US$762.42; which equates to a savings of US$586.71 per cycle of treatment). Over a median of six treatment cycles of weekly taxane therapy, this would results in a cost savings of approximately US$3520 per patient.

Discussion

A prospective time and motion study was conducted in MBC patients receiving Abraxane® or Taxol® in one of three cancer clinics located in the People's Republic of China. The findings revealed that Abraxane® had a significant impact on reducing materials, personnel, total time, and over costs for drug delivery. Patients receiving Taxol® were also five times more likely to develop an acute adverse event (odds ratio = 5.6; $p = 0.12$), despite the use of recommended prophylaxis.

The intent of the current study was to measure health care resource use, safety, and the total cost for drug delivery. As a result, the cost of drug acquisition was not included in the analysis because this was not a cost utility study. A cost utility analysis would have required the collection of both direct and indirect costs, overall survival, and differences in health state utilities between Abraxane® and Taxol®. Such a study in patients from China has not been published to date. However, pharmacoeconomic evaluations comparing Abraxane® to both paclitaxel and docetaxel in Canada, the United Kingdom, Italy, and Spain have been published.[7,18–20] The first published economic evaluation of Abraxane® in MBC was the Canadian study by Dranitsaris et al.[7] The investigators developed an economic model and populated it with clinical, side effect, cost, and health state utility data to compare Abraxane® to docetaxel, both as alternative to paclitaxel for the first line treatment of MBC. When all of the relevant direct costs were quantified, Abraxane® had comparable costs to docetaxel (CND$15,105 vs. CND$15,268; in 2008 CND$). When health state utilities were considered and both agents were evaluated as alternatives to generic paclitaxel, the incremental cost per quality adjusted life year gained (QALY) was more favorable with Abraxane® than with docetaxel (CND$56,800 vs. CND$739,600 per QALY). The investigators concluded that Abraxane® would be an economically attractive alternative to docetaxel in MBC patients. As an alternative to paclitaxel, a US$56,800 cost per QALY also appears to represents good value based on current cost effectiveness thresholds.[7] Similar conclusions were also derived from the pharmacoeconomic evaluations conducted in United Kingdom, Italy, and Spain.[18–20] Notwithstanding, a full cost utility analysis, which includes the collection of quality of life data in breast cancer patients, it currently being undertaken from a Chinese health care perspective. The resource use data gathered from the current study will be used to support the cost utility analysis, which should be completed by the second quarter of 2014.

There are a number of limitations in the current study that need to be addressed. The sample size was small, which limited our statistical power. Therefore, additional data from other cancer centres in China should be collected to provide more statistically robust conclusions. Patients in the Abraxane® or Taxol® groups were not randomly allocated. As a result, there was imbalance in potentially important variables such as sites of metastatic disease, patient performance status, dosing schedules as well as treatment center. Such imbalances could have contributed to patient selection bias, compromising the final results. The development of acute adverse events was numerically higher in patients who received Taxol®. However, the difference was not statistically significant, nor was the study adequately powered to detect such

differences. The analysis only focused on health care resources for drug delivery and did not consider treatment preferences, health state utilities and differences in acquisition cost between the two drugs. However, a cost utility analysis, which included a health state utility assessment in Chinese breast cancer patients, has been completed, an abstract will be presented an international meeting and a manuscript describing the results has been submitted for publication.[21] The cost of chronic long-term toxicity was not part of the cost comparison. There are several generic formulations of paclitaxel available in China. However, because of uncertainly in overall product quality, the analysis was relative to the branded paclitaxel formulation (i.e. Taxol®). Lastly, the sample size was small and was obtained from only three oncology clinics. As a result, the findings from this study may not be fully generalizable to other cancer clinics in China.

To our knowledge, this is first such study in breast cancer patients to be undertaken in China. The findings revealed that Abraxane® was associated with fewer acute adverse drug reactions and significant reductions in health care resources, physician/nurse time and costs for overall drug delivery compared to Taxol®. Given the high patient volumes currently faced by many cancer centers in China, Abraxane® would have a major impact on the delivery of timely and efficient care to patients with MBC.

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Conflict of interest

None declared.

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