Title Page

Title: Evaluation of The Performance Of Elastomeric Pumps In Practice: Are We Under Delivering On Chemotherapy Treatments?

Short Title: Variation in Infusion rate duration of Ambulatory Chemotherapy Regimens

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Ethical approval to conduct both phases was sought and granted from the Clinical Audit committee at the Royal Marsden NHS Trust.

Abstract

Elastomeric pumps are widely used to facilitate ambulatory chemotherapy, and studies have shown that they are safe and well received by patients. Despite these advantages, their end of infusion time can fluctuate significantly. The aim of this research was to observe the performance of these pumps in real practice and to evaluate patients' satisfaction. This was a two-phase study conducted at three cancer units over 6 months. Phase-1 was an observational study recording the status of pumps at the scheduled disconnection time and noting remaining volume of infusion. Phase-2 was a survey of patients and their perception/satisfaction. Ethical approval was granted. 92 cases were observed covering 50 cases disconnected at hospital and 42 disconnected at home. The infusion in 40% of hospital disconnection cases was slow with patients arriving at hospital with unfinished pumps. 58% of these had an estimated remaining volume which exceeded 10mL with 35% exceeding 20mL. In 73% of these cases, and regardless of the remaining volume, the patient was disconnected and the pump was discarded.

To conclude, the performance of pumps varied, which affected nurse workload and patients' waiting-times. A smart system is an option to monitor the performance of pumps and to predict their accuracy.

Keywords: Ambulatory Chemotherapy, Ambulatory Infusion Pump, Elastomeric Pumps, Safety, Colorectal Cancer, Fluorouracil, 5-FU, FOLFIRI, FOLFOX.

Introduction

Background:

With the advent of elastomeric pumps (EPs), ambulatory chemotherapy (AC) has become the preferred choice of treatment for many regimens (Gorski & Grothman 1996). Ambulatory chemotherapy services have had a significant positive impact on patients' quality of life (QoL), staff workload and NHS costs (Dougherty et al. 1998). Despite these advantages, the accuracy of infusion time of these pumps can fluctuate significantly and is dependent on several factors such as temperature and viscosity (Salman et al. 2013).

With many different environmental factors influencing the accuracy of these pumps, it is nearly impossible to model the exact environment that duplicates conditions experienced during standard clinical practice. Fluctuations in elastomeric pumps performance may affect the total chemotherapeutic dosage delivery time, patients' waiting time, satisfaction and quality of care. Therefore, there was a need to evaluate the performance of these pumps in real practice.

To date, the reliability and accuracy of EPs in laboratory based settings has been investigated in several previous studies (Chung et al. 2001; Thiveaud et al. 2005; Ackermann et al. 2007; Wang et al. 2012).

However, there are very few studies evaluating EP performance in practice. Hardy et al (15) investigated the accuracy of 6 ambulatory infusions, 5 electric and one elastomeric pump. The elastomeric pump (Baxter®) was the least accurate pump with a relative error in infusion time of -5 to +13%. It was demonstrated that patients preferred the Parker-Strato 2100, an electronic pump (Hardy et al. 1995). Cassano-Piché et al surveyed clinicians regarding

patients receiving AC and including the number of incidents related to EPs (Cassano-Piché et al. 2012). Findings of this study reported a total of 46 incidents (out of 213 incidents), such as pumps failure and incorrect flow rate, during the administration of medications using EPs (Cassano-Piché et al. 2012).

Impact on Clinical Practice:

The findings of these studies left many unanswered questions related to the accuracy of EPs in standard clinical practice. Would the flow rate of pumps fluctuate more in practice than that specified by the manufacturer? Would the variation in flow rate of pumps affect patients' satisfaction, waiting times or the overall treatment management? Since the performance of EPs is unpredictable, the end of infusion time can vary resulting in patients arriving for disconnection with unfinished pumps. Nurses may then ask patients with unfinished pumps to wait for hours not knowing for certain if the pumps will complete the infusion at all. To date, AC has not been evaluated from this point of view as previous studies have mainly focused on QoL in relation to receiving treatment at home and not the effect of variation in pumps (which can increase patients waiting times). Fluctuations in elastomeric pumps performance may therefore affect patients' satisfaction and quality of care. Previous studies have reported that waiting times are a major factor affecting patient satisfaction (Anderson et al. 2007; Dansky & Miles 1997; Michael et al. Leddy et al.). . Dansky and Miles (1997) have suggested that informing the patients how long they have to wait may improve the patients' satisfaction (Dansky & Miles 1997).

Current Practice:

This audit was based on the hypothesis that if the performance of elastomeric pumps varies, patients might have to wait in the medical day unit (MDU) for the pumps to finish eluting or go back home and then return to the MDU the next day. Patients who normally have their

pumps disconnected at home by a district nurse, have to rearrange their appointments, which inconveniences both patients and nurses.

The regimens evaluated in this study were FOLFOX and FOLFIRI for the treatment of colorectal cancer, which is the most common cancer treated using AC-EPs in the UK (Mabro et al. 2006; SEESURN 2012; Field et al. 2008). Fluorouracil (5-FU) is currently administered, as a 48 hour continuous infusion using EPs, as part of the FOLFIRI and FOLFOX-6 regimens (Wang et al. 2007; Seifert et al. 1975).

Fluorouracil

5-FU is known to have a short half-life of 5-20 minutes in plasma, and a narrow therapeutic window (Undevia et al. 2005; Blaschke et al. 2011; Ackermann et al. 2007). It was reported by Blaschke et al (2011) that when calculating the ideal dosage of 5-FU, minimising toxicity while maintaining optimum therapeutic effect remains challenging. They found 5-FU to have a narrow therapeutic window of 18-25 mg/h/l and that its plasma concentration was affected by higher and lower doses (Blaschke et al. 2011). Thus, depending on each regimen and the chemotherapeutic agent's pharmacokinetics properties (half-life), variation in the performance of elastomeric pumps may therefore affect the treatment outcome.

For the above reasons, the aim of this audit was to evaluate the performance and accuracy of elastomeric pumps in standard clinical practice and the action taken with unfinished pumps. The audit also aimed to evaluate patient waiting times to disconnect their pumps, patients' satisfaction and perception of current elastomeric pumps and overall AC services.

Materials and Methods

This two-phase audit observed and evaluated patients receiving AC (5FU infused via a 48 hour elastomeric pump) at three gastrointestinal medical day units (MDU), one at each of the three Royal Marsden NHS Trust sites.

Both phases were conducted from September 2013 to March 2014. Approval to conduct both phases was sought and granted from the Clinical Audit committee at the Royal Marsden NHS Trust.

a. Phase I

Phase I was an observational cross-sectional study. A data collection sheet was designed to capture the required data. Patients were observed at connection and disconnection in the MDU and the remaining volumes were visually estimated by the researcher using a pictorial guide produced by the researchers). Some patients were observed several times counting each treatment cycle/disconnection time as a case study. The observational tool was divided into 5 sections (A-E) as shown in Table 1. Ay further information gathered from the patients was also considered such as reasons behind unfinished pumps i.e. Cold weather, blocked catheter etc. Furthermore, any information given to patients by the nurses regarding their unfinished pumps was recorded

b. Phase II

Phase II was a survey of the encountered patients' perceptions on elastomeric pumps. The questionnaire was designed to capture all relevant data, and it was divided into 5 sections (A-E).

• Part A: Patient experience with pump (Figure 1), this includes

o The number of times of using elastomeric devices

o Previous pump performance i.e. if the pump finished on time, leakages or stopped working.

• Part B: Hospital policy regarding unfinished pumps covering the patients' previous experience.

• Part C: Any incidents with pumps such as leakages inside or outside the pump using closed ended questions.

• Part D: Assessment of patient perception and satisfaction with the performance of elastomeric pumps.

• Part E: This section was designed to provide the patients with the space to reported any other incidents or suggest improvements.

All patients observed in Phase I were asked to complete the survey.

c. Data Analysis

Confidentiality across both phases was maintained. All data collected from both phases I & II were anonymised and analysed using Microsoft Excel (2010) software. Infusion time duration was the dependent variable that was measured within this study. Mean, standard deviation, median and percentage of incidents were also calculated.

The data collected via the survey was analysed using descriptive statistics. Results collected from Phase I and II were synthetized for overall conclusions and recommendations.

Results

For Phase I, 92 cases were followed covering 50 cases disconnected at MDU and 42 at home by district nurses. For Phase II of the study, 65 patients completed the questionnaire covering 500 cases of using the elastomeric pumps. Equal distribution between male and female patients was observed with a median age of 64 and a range from 29-88 years old. FOLFIRI and FOLFOX, the two major therapies monitored, had a median cycle of treatment per patient of 4 and a range of 1-12 cycles. 66% of cases had peripherally inserted central catheter (PICC) lines while the remaining 34% had Port lines.

Phase I results and the performance of elastomeric pumps

From the fifty disconnections observed at the MDU (Table 2), 25 (50%) finished on time with a margin of ± 59 minutes, 5 (10%) finished faster (<48 hours) and 20 (40%) needed more time as the infusion was slow (> 48 hours). For the fast pumps, 3 cases (6%) finished earlier than expected by approximately 2 hours and 2 cases (4%) had an unknown infusion time.

The slow pumps (40% of cases) were either allowed to finish infusing or discarded (summarised below). The former were left to infuse for an average of 5 extra hours with a range of 1 to 18 additional hours.

 The remaining infusion volumes at approximately 48 hours varied with 43% of the slow pumps having 10 mL or less (Total planned infusion volume= 120 mL, Table 2). The remainder of the slow pumps (57%, Table 2) had more than 11 mL remaining with 19% having more than 30 mL. During the observations, it was noted that the remaining volumes in the unfinished pumps were often under- estimated by the nursing staff. Furthermore, the

nurses fed back estimations to the patients and recorded the infusion as complete in the patients' records. No leakage incidents were observed, however, high condensation levels were often observed between the plastic rigid container and elastic reservoir.

Observing the performance of elastomeric pumps disconnected at home (n=42) was not feasible. Therefore, patients were phoned 48 hours after connection to check on the status of their pumps. Patients reported over the phone that 48% of cases were disconnected on time (48 hours), 47% of cases were disconnected after 48 hours (average= 50 hours) and only 5 % of cases were disconnected before 48 hours (average of 1 hour earlier).

Action taken with unfinished pumps

It was observed that there was no formal policy guiding the actions of health professionals regarding unfinished pumps. In fact, before conducting this audit, this was not recognised as an issue of concern. Results revealed that pumps with over 20 mL of infusion remaining were generally considered as unfinished by the nurses. Due to the absence of a policy, the nursing staff had various approaches towards unfinished pumps (Table 2). The different approaches that were observed are as below:

- 65% of these pumps were discarded immediately. 70% of these pumps had less than 20 mL of infusion remaining, however the rest of the pumps had up to 30 mL of infusion remaining)

- In 15% of the cases, the patient was asked to wait in the MDU to allow the pump to infuse further

- In 10% of the cases, the patient was sent home and asked to come back the next day

- In 10% of the cases, Patient was given advice over the phone**.**

Patient waiting times

Some of patients returning after 48 hours with unfinished pumps were asked to wait either at

- MDU: 15% of unfinished pumps

Patients' waiting time for these incidents was in the range of 30 – 60 minutes with approximately 20 mL left over infusion.

- Home: 20% of unfinished pumps

Patients who were sent home and asked to return to the MDU had their pumps connected for 64-68 hours. This translates into an additional 16-20 hours for their infusion to complete. Furthermore, one of the pumps was discarded after 16 hours of delay with more than 30% of the infusion remaining. Consequently that patient did not receive the full desired dose even after the long wait.

Phase 2

Of the 65 patients who completed the survey, reported the infusion did not finish at the expected time in 21% of the cases. Of these, 17% were due to slow infusion rate; the remaining 4% were due to either fast infusion rate (3%) or to pump failure (1%).

For 52% of the cases, patients came back to the hospital to disconnect their pumps. For 42% of the cases, patients stayed at home and their pumps were disconnected by the district nurses while the remaining 4% of the cases patients disconnected their pumps by themselves.

Furthermore, none of the patients s experienced any leakage inside or outside the elastomeric pump and there were 5 cases where the pump stopped working completely.

For patient satisfaction, the participants were asked to rate their satisfaction with the elastomeric pumps and the service in general. 34% indicated they were satisfied while 64% indicated they were very satisfied.

Moreover, patients were asked to provide more information about how they are handling their pumps while they are at home and during their daily routine activities. These are summarised in Table 3.

Discussion

This paper demonstrates the performance and accuracy of elastomeric pumps in practice for the treatment of colorectal cancer. The performance of elastomeric pumps was shown to be variable affecting the total dose administered to the patients (in the case of slow pumps) as a significant percentage of unfinished pumps were discarded.

Chemotherapeutic dosage infusion time in practice:

40% of the observed disconnections were slow pumps with a 2-38% deviation in elution time in practice. This is significantly higher than the manufacturer specification of 10% (Baxter clinician guide, 2014). In 57% of the unfinished infusions, the pumps were discarded translating into patients not receiving the planned dose , (loss of 4-25% of the planned dose). With a direct concentration-response rate association, keeping the level of 5-FU in the plasma within the therapeutic window is crucial for optimal survival rates (Gamelin et al. 1996; Gamelin et al. 2008; Gamelin et al. 1998; Ychou et al. 2003). It was reported previously that the treatment outcome might be affected with a 15% reduction in the chemotherapy dose (Sewell 2006; Bonadonna et al. 1995).

Impact of infusion time variation in practice

Variation in the pumps' performance also affected both nurses' workload and patients' waiting times. Nurses had no formal policy to guide their response to unfinished infusions at 48 hours. Moreover, the nurses' visual inspection used to estimate the volume of left over infusion was underestimating the actual volume.

Slow infusion rate (infusion more than 48 hours)

Slow infusion rate translated into patients receiving less than 75% of the prescribed 5-FU dose which is beyond the acceptable 10% margin of error (Sewell 2006; Plumridge & Sewell 2001). These cases resulted in patients receiving sub-therapeutic dosing.

Fast infusion rate (infusion less than 48 hours)

There was a challenge with recording fast pumps as patients were returning to MDU before their scheduled appointments with already finished pumps so the exact infusion time could not be recorded. These cases were still considered as fast, however as no attempts could be made to estimate the end of infusion time the pumps were categorised as <48 hours-unknown.

Feedback from patients disconnected by district nurses

It is important to note that in cases of late pump disconnection (47%) this may not be because of the slow infusion; it could be that the pump infused on time but the district nurse arrived few hours later. It was hypothesised that the district nurses estimation of the remaining infusion may well be similar to those nurses estimation in the MDU. Therefore, pumps regarded as finished may have had infusion remaining when disconnected.

Comparison between Phase I and II

Findings from the patients' questionnaire contradict those of observational study. Results of the patients' questionnaire report fewer incidents of elastomeric pumps not finishing on time (both fast and slow pumps). The percentage of pumps finishing after 48 hours was approximately halved when the results were reported by patients (Phase II) as opposed to observed at disconnections (phase I). This might be due to the under-estimation of the remaining infusion volume by the nurses. Therefore, patients may have reported unfinished pumps as finished basing their conclusions on the received positive response regarding their pumps performance.

Smart system

The survey of current AC services demonstrated a high percentage of patient satisfaction. However with the many factors influencing the performance of these pumps and the impact on the treatment management, there is a need for innovation in this field. Currently, a prototype "smart" system has been developed that is capable of using digital imaging to evaluate the performance of these pumps in real-time. This provides feedback to both patients and healthcare professionals in an effort to achieve a more proactive approach capable of detecting significant alterations in infusions early on (Salman et al, 2015) Implications for Practice and Conclusion

The findings of this audit have highlighted areas where AC services can be improved. To address this in practice, several actions can be taken such as raising awareness amongst health professionals involved in AC services and implementing a policy for action to be taken in the event of pumps not finishing at 48 hours. This should also be coupled with an educational campaign for health professionals. This can include practical approaches to estimate remaining volume in the pump such as using a poster/handout/memo with pictures

of the pump filled with different volumes of solution or the use of balances to weigh the pumps. It is also recommended to update the patient information leaflet with a new section entitled "Is your infuser working?". This section includes pictures of the pump with known volumes of left over infusion and what to do in the cases of interrupted infusions. It could also be printed as a flyer and placed with the pump in the infusion bag.

Limitations

Even though this audit highlighted an unreported problem with unfinished infusors being discarded, a bigger study with a larger sample size, different type of infusors and longer observation would have provided more insight into the problem. Moreover, the visual estimation of the remaining volume used in the methodology is not precise and using a balance would have circumvented this limitation. This was addressed in a follow up study reported elsewhere.

This paper has summarised the findings of a clinical audit that highlighted a concern with ambulatory chemotherapy where a significant proportion of patients not receiving their planned doses. The issue is further compounded by the fact that it is not documented in the patient notes nor is the prescriber notified. This concern should also be investigated in other uses of Eps such as antimicrobials. Raising awareness about this discrepancy may help address the problem through institutional policies, health professional and patient education.

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Transparency

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Table2

Infusion time observed	Percentage observed (%)	
Infusion finishing on time	50	
Infusion finishing before 48 hours (fast pumps)	10	
Infusion finishing after 48 hours (slow pumps)	40	
Infusion failure	0	
Infusion Leakage	0	
Volume remaining in the pumps at disconnection time (mL)	**Delivered dose**	**Percentage observed (%)**
< 5	> 96	15
5-10	< 96	27
11-20	< 91	23
21-30	< 83	15
> 30 mLs	< 75	19

Table 3

Patients' activities and handling of elastomeric pumps	Percentages (%)
Patients sleeping with the pump while keeping it in the bag around their waist	26
Patients sleep with the pump near pillow	11
Patients sleep on the pump	5
Patients shower with the pump	9
Home temperature can go above 25°C	3
Home temperature below <10°C at night	2
Patient know/record temperature of house	25