Valentina Pecoraro*, Luca Germagnoli and Giuseppe Banfi

Point-of-care testing: where is the evidence? A systematic survey

Abstract: Point-of-care testing (POCT) has had rapid technological development and their use is widespread in clinical laboratories to assure reduction of turn-around-time and rapid patient management in some clinical settings where it is important to make quick decisions. Until now the papers published about the POCT have focused on the reliability of the technology used and their analytical accuracy. We aim to perform a systematic survey of the evidence of POCT efficacy focused on clinical outcomes, selecting POCT denoted special analytes characterized by possible high clinical impact. We searched in Medline and Embase. Two independent reviewers assessed the eligibility, extracted study details and assessed the methodological quality of studies. We analyzed 84 studies for five POCT instruments: neonatal bilirubin, procalcitonin, intra-operative parathyroid hormone, troponin and blood gas analysis. Studies were at high risk of bias. Most of the papers (50%) were studies of correlation between the results obtained by using POCT instruments and those obtained by using laboratory instruments. These data showed a satisfactory correlation between methods when similar analytical reactions were used. Only 13% of the studies evaluated the impact of POCT on clinical practice. POCT decreases the time elapsed for making decisions on patient management but the clinical outcomes have never been adequately evaluated. Our work shows that, although POCT has the potential to provide beneficial patient outcome, further studies may be required, especially for defining its real utility on clinical decision making.

Keywords: clinical decision making; clinical outcome; diagnostic applications; evidence; patient management; point-of-care testing; quality of reporting.

Background

Point-of-care testing (POCT) is referred to a near patient, bedside, or extra laboratory testing. It is likely to be carried out by unspecialized staff. By providing results quickly this technology could improve some aspects of laboratory organizations in areas such as emergency rooms, operating rooms and intensive care, but also in mobile vehicles and during transport of patients [1].

A wide number of laboratory tests are now available in different POC devices used for a broad spectrum of diagnostic applications. Several aspects are associated with the rate of POCT implementation [2] such as the reduced complexity of device, type of biological matrices and the high cost, but it is not clear whether the technology has been developed in response to clinical need or whether marketing strategies have led to the perception that this technology is needed. The availability of faster test results should speed diagnosis and treatment, both of which should have a positive impact on patient care. These benefits might also be expected to reduce the amount of time spent by patients waiting in an emergency department and they could reduce the turn-around-time (TAT) of some results, improving patient management [1].

Laboratory professionals more often paid attention to technological aspects of POCT, but there is an increasing interest in its potential clinical outcomes [3]. This emphasis is derived by the need of the adoption of an evidence-based approach for the introduction of new technologies (health technology assessment), and now there is a little evidence that POCT is really improving patient outcomes although rapid supply of results could facilitate clinical decision making [4, 5].

In literature there are many studies comparing POCT and traditional laboratory technologies. Furthermore, organizations and scientific associations have produced a numbers of documents and guidelines to promote the better use of these devices [6, 7]. The purpose of our work is to analyze the scientific literature and identify studies that assess the impact of the POCT on relevant clinical outcomes through a systematic process. The POCT
instruments considered were neonatal bilirubin (Bil), procalcitonin (PCT), parathyroid hormone (PTH), troponin (Tn) and blood gases analyzer (BGa).

**Methods**

**The survey process**

The survey was carried out in two steps identified as phases 1 and 2. We applied the systematic methodology suggested by the Cochrane Collaboration to our survey [8].

**Phase 1: identification of studies**

In phase 1 the assessors have formulated the specific questions about each POCT would be evaluated.

1. Do the measurements of neonatal Bil decrease the number of transfusions and influence the phototherapy practice?
2. Do the measurements of PCT decrease the incidence of major infection and modify the antibiotic therapy?
3. Does the intra-operative PTH assay reduce the number of re-interventions?
4. Does the measurement of Tn decrease the number of myocardial infarctions, mortalities and length of stays (LOSs)?
5. Does BGa in operating and intensive therapy room decrease the incidence of cardiovascular events?

The pathway included four steps: the assessment of the eligibility criteria, the search in major database, the selection of studies and extraction of data. For each type of POCT the authors have searched the studies and extracted major information.

**Eligibility criteria**

Studies were included if they met the following criteria: 1) Studies randomized, quasi-randomized, prospective or retrospective cohort and case-control; 2) Specimens analyzed by POCT and standard laboratory procedure; 3) Comparison of results between POCT and laboratory instruments; and 4) Report of results of at least one relevant outcome.

The term ‘quasi-randomized’ refers to controlled trials that use inappropriate randomization strategies [9].

We were very ‘inclusive’ to reach a pragmatic overall picture of the research status in this field.

**Database search for published studies**

Studies were identified by searching electronic database and scanning reference lists of articles. This search was applied to Medline (1990–May 2012) and adapted for Embase (1990–May 2012) to capture all potentially relevant English language scientific papers. We considered also the reference list of all potential eligible studies. Databases were searched using the following search terms: point of care testing or point-of-care-testing or POC and troponin or bilirubin or procalcitonin or parathyroid hormone or blood gas analyzer.

**Selecting published studies**

The literature search was conducted by one investigator (VP). Two researchers (VP or LG) selected independently eligible studies for inclusion. Disagreements between reviewers were resolved by consensus. The abstracts were appraised and publications were selected or rejected based on the inclusion criteria. The full texts of the remaining publications were obtained. Each potentially relevant full text was examined in more detail by all the authors.

**Data extraction**

Information was extracted from each included studies about: 1) characteristics of study: study design, year, country where the study was performed; 2) characteristics of samples (age, sex, number of sample for each patients, initial and final accrual time); 3) patient important outcome: TAT, LOS, mortality, number of infections, number of re-interventions, recurrence of hyperparathyroidism, major complications; 4) diagnostic accuracy outcomes: sensitivity (Sn), specificity (Sp), likelihood ratio (LR), positive predictive value (PPV), negative predictive value (NPV).

A ‘patient important outcome’ is an event that has an impact on the patient health status and, when its frequency changes, it becomes of value for the patient [10].

Two authors (VP and LG) independently extracted data from studies and entered in the data extraction form. Disagreements were resolved by discussion.

**Phase 2: quality of reporting**

In phase 2, the full texts of the included studies were evaluated by two assessors who extracted the relevant information to complete the quality of the reporting checklist.
We moved from the risk of bias tool of the Cochrane Collaboration. As this instrument was created for evaluating randomized controlled trials (RCTs), we slightly adapted it to non-randomized studies (NRS). As reported in the Cochrane Handbook, risk of bias assessment criteria for these trials is not well established [9, 11].

We decided to assess the risk of bias in the following domains: 1) Study designs, i.e., if the study was retrospective or prospective, awarding a low risk of bias to prospective trials; 2) Outcomes reported, i.e., studies including important patient outcomes, as well as LOS and TAT, were evaluated; 3) Blinding, i.e., the outcomes’ assessors were blinded, awarding at low risk of bias; 4) Control of known confounding factors at baseline, i.e., samples were selected ad hoc at the beginning of the study, considering at high risk of bias the trials that performed this method.

Every domain could be classified as ‘high’ or ‘low’ risk of bias. If the information reported in the paper was not enough, the domain was defined as ‘unclear’. Methodological quality was independently assessed by two authors (VP and LG). Disagreements were resolved by consensus.

Results

Study selection

Our literature search identified 456 references: 37 about Bil, 26 about PCT, 10 about PTH, 65 about Tn, and 318 about BGa. Exclusion of duplicates and irrelevant references deleted 99 records. After screening of abstract, 116 studies proved to be eligible for inclusion and their full texts were analyzed in more detail. Thirty-two were excluded because: 1) no comparison with laboratory existed (n=10); 2) did not evaluate POCT (n=10); 3) were narrative review (n=11); and 4) were replaced (n=11). Finally we included 84 studies: 19 Bil [12–30], four PCT [31–34], six PTH [35–40], 25 Tn [41–65], 30 BGa [66–95] (Figure 1).

Study characteristics

The included trials corresponded to seven RCT [46, 49, 50, 52, 57, 62, 83], 56 prospective studies [12–23, 25, 26–30, 31–35, 37–41, 43–45, 47, 48, 51, 53, 55, 56, 58–61, 64–67, 71–74, 76–78, 81, 82, 87, 91], three retrospective [42, 54, 94], one case series [36] and before and after study [63], 16 experimental and cohort studies [24, 68–70, 75, 79, 80, 84–86, 88–90, 92, 93, 95] not better defined. Main features of the studies are summarized in Table 1. Overall, 50,586 sample were considered. Twelve studies were published each from 2010 and 2011, five in the 2009, eight in the 2008, 43 between 2000 and 2007, and 16 before 2000. Thirty-eight studies were published in USA, seven in Germany, six in France, five in the Netherlands and Australia, three in Japan and the UK, two in China, Italy and Switzerland, one each Austria, Belgium, Canada, Denmark, Finland, NC, Singapore, Spain, Sweeden, Taiwan and Turkey.

Seventeen out of 84 studies (20%) reported diagnostic accuracy outcome (Table 1), eight studies about Tn, five studies about Bil, two about PCT and BGa.

Patient important outcomes

There is insufficient evidence that transcutaneous Bil measurement reduces the number of transfusions. No data concerning the possible decrease of transfusion and influence on phototherapy practice exist. Four studies about PCT matched the inclusion criteria and only two reported the number of bacterial infections [32, 33]. No data concerning modification of antibiotic therapy exist. Only one [38] out of six studies about PTH evaluated reduction on TAT and LOS. The study of Chou et al. [36] reported numbers of re-interventions (two patients had a secondary operation) and surgery complications. The majority of studies considered ‘important patient outcome’ is in the Tn group: eight out of 25 studies (32%) evaluated reduction on LOS, of these seven considered also TAT. Six studies (7%) reported number of patients afflicted by myocardial infarction and four studies (16%) reported data about the mortality. POCT is reported to decrease LOS and TAT about 26 and 56 min, respectively. Studies concerning BGa are experimental studies reporting diagnostic accuracy outcome and did not report data of possible decrease of incidence of cardiovascular events through the use of such a method (Table 2).

Risk of bias within studies

Risk of bias evaluation is reported in Figure 2. Most of studies are prospective so the study design was judged as low risk (green). Many items were judged as unclear (reported in yellow) because the studies did not report enough information for a proper evaluation. In most trials the blinding of outcome assessment was at high risk of bias (red).
Discussion

This is the first systematic survey which explores evidence of POCT impact on clinical decision making. We analyzed five POCT instruments measuring neonatal Bil, PCT, PTH, Tn and BGa. The studies evaluated were principally observational studies which correlated laboratory and POCT results. The devices should help the clinical decision making, but only 10 out of 84 studies considered important patient outcomes. The reported quality was generally low; an absence of information about outcome assessment was usual.

The increase of POCT during the last 10 years has been made possible by a number of factors, including advances in computer technology. As POCT methods and instruments require low quantity of biological materials, they are easy to use, smaller and portable, produce results on a variety of analytes more quickly than traditional laboratory instruments, their use appeals to both the medical and nursing or laboratory staff. This advantage does not always mean better patient outcomes, the medical unit that would like to perform POCT should be interested in the real impact of results in clinical practice, besides the accuracy of devices. Kendal et al. [1] have designed
Table 1 Characteristics of studies included.

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Study design</th>
<th>Country</th>
<th>Number of samples</th>
<th>Diagnostic accuracy outcome</th>
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<td>France</td>
<td>473</td>
<td>NR</td>
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<td>USA</td>
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<td>NR</td>
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<td>4689</td>
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<td>China</td>
<td>113</td>
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<td>USA</td>
<td>NR</td>
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<td>USA</td>
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<td>USA</td>
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<td>Prospective</td>
<td>Sweeden</td>
<td>851</td>
<td>SN, SP, PPV, NPV, LR+, LR-</td>
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</table>
a randomized controlled trial to assess the accuracy and reproducibility of the results of the test and clinical outcome. They reported that POCT produced a time critical benefit for 7% patients and POCT influenced treatment in 14% of cases overall. Also, there were no difference in the amount of time spent in the emergency department, LOS and mortality. They concluded that POCT results would result in a clinical important reduction in the time elapsed in clinical differential diagnosis and treatment decision, but the methodology of studies should be improved.

The role of the POCT concerns the help in making clinical decisions. Several studies have investigated the

Table 2 Number of studies reporting data about important patients’ outcome.

<table>
<thead>
<tr>
<th>n</th>
<th>TAT</th>
<th>LOS</th>
<th>Mortality</th>
<th>Several bacterial infection</th>
<th>Number of re-intervention</th>
<th>Recurrence of hyperparathyroidism</th>
<th>Major complication</th>
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<td>19</td>
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<td>0</td>
<td>0</td>
<td>–</td>
<td>–</td>
<td>–</td>
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<tr>
<td>PCT</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>PTH</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>–</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Tn</td>
<td>25</td>
<td>7</td>
<td>8</td>
<td>4</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>BGa</td>
<td>30</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>TOT</td>
<td>84</td>
<td>10</td>
<td>9</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

BGa, blood gas analyzer; LOS, lost to follow-up; PCT, procalcitonin; PTH, parathyroid hormone; TAT, turn-around-time; Tn, troponin. n, number of studies included in each group of POC.
implementation of these POCT devices in a clinical setting. Altinier et al. [96] evaluated POCT for cardiac markers in the emergency department. POCT can reduce TAT and allow rapid provision of results. However, there are not RCTs to determine whether the devices can change patient management and reduce hospital admission. POCT are often used for self-monitoring of oral anticoagulation and its use leads to a significant reduction in death but also in major clinical events. The study of Ryan et al. [62] explored if POCT decreases the LOS of patients in emergency department. The authors conclude that POCT had the potential to reduce time in decision making, in fact POCT decreases the proportion of test results available to the physician within 30 or 60 min. The results demonstrated variable benefits of POCT and, when benefits were evident, they were not as extensive as it might be assumed from the concept that rapid results are translated into a rapid decision.

We evaluated biochemical tests which are common in clinical practice, but POCT are not implemented routinely for these tests, with the exception of blood gas. The most common test for which POCT is available is the measurement of glycated hemoglobin, employed in monitoring of diabetes patients. Although the test is used daily in clinical setting, a recent systematic review of Al-Ansary et al. [97] concluded that there is not enough evidence of the effectiveness of POCT for glycated hemoglobin due to some limitations of the studies design. Similarly, new technologies were implemented to simplify parathyroidectomy surgery. Previews studies have clearly shown that this approach leads to successful clinical outcomes and some suggest that it can lead to decrease costs through less exposure to anesthesia and shorter hospital stays [38]. Our survey, instead, included six studies about PTH and only one (Chou [36]) reported the number of re-interventions.

Overall, there are different opinions regarding the issue of POCT implementation. Several studies support POCT as an alternative to laboratory [61, 98] reporting good concordance such as Bil, while others find little discrepancies in comparisons [47].

Although there is an improvement of patient management when using POCT, there are not RCTs concerning the relationship between physician decision and patient improvement. Our results show that only 13% of studies evaluated important outcome and the measures were not assessed masked. It is not always possible to blind physician and patients because the clinical decision is made at the time the result is produced. However, blinded measurement and reporting of outcome are possible.

Most of the published studies evaluated measurements in the clinical pathway which are surrogate outcomes. Surrogate outcomes are outcomes for which changes do not directly impact the patient’s disease status or well being, but which are theoretically tied to the patient’s disease process management [10]. Surrogate markers include changes in laboratory parameters (e.g., cholesterol levels as a surrogate for myocardial infarction). Authors may be tempted to use surrogate endpoints because they usually occur more frequently than patient important outcomes. Use of surrogate markers requires complete confidence that each outcome correlates consistently with a patient important outcome (i.e., survival) [10]. Sometimes the surrogated outcome may not be casually or strongly related to the clinical outcome, but it can be only a concomitant factor, and thus it may not predict the effect on the clinical outcome [99]. La Cour et al. [100] reported that one in five randomized controlled trials used surrogate outcomes as a primary outcome and highlight that a correct report and evaluation of surrogate outcomes is needed.

We observed some noise in the use of these devices, emphasizing the additional issue that should be addressed in future studies: 1) there is insufficient evidence of the effectiveness of POCT in clinical decision making; 2) the current literature requires further development; and 3) economic analysis exploring whether the potential benefit of POCT justifies the additional cost is needed.

Our findings suggest that POCT may be clinically beneficial for some presenting complaints. Further studies are required for investigating the economic and clinical benefits of POCT and these studies are crucial for the definition of the efficacy of POCT in the clinical setting. However, even trials based on validated surrogate outcomes may not be able to capture unexpected important harmful effects of the implementations of technology.

Our results are in line with the National Academy of Clinical Biochemistry Laboratory Medicine Practice Guideline [7]. The document offers recommendation to improve the analytical performance and clinical utility of POCT by reporting the evidence about some instruments. Authors reported evidence about the major POCT used in clinical practice and highlighted the limited available evidence for some of these (i.e., Bil) and concluded the need to provide a better link between POCT and patient outcome.
We studied literature concerning POCT which have possibly real impact on clinical decisions, especially for emergency department (Tn, BGa, PCT), surgery (PTH), and internal medicine (Bil). Surprisingly, we did not find specific literature based on RCTs and cost-effectiveness studies, even for very common POCT devices, as glucometers or urine analyzers.

Moreover, the wide acceptance of common marketing appeal for POCT devices, particularly for the tests we studied, is not really evidenced by published studies, although in some cases, e.g., BGa, their number is very high. A complete redefinition of aims and methodology of studies devoted to POCT should be acknowledged.

A careful appraisal of the impact of its use in clinical practice should be carried out. Randomized controlled trials are needed to investigate the impact of the test on patient management and outcomes.

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