Longitudinal changes in the use of PD Assistance for patients maintained on Peritoneal Dialysis

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Abbreviations used

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>CGA</td>
<td>Comprehensive Geriatric Assessment</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence intervals</td>
</tr>
<tr>
<td>HD</td>
<td>Hemodialysis</td>
</tr>
<tr>
<td>IQR</td>
<td>Interquartile range</td>
</tr>
<tr>
<td>PD</td>
<td>Peritoneal dialysis</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
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</table>
Key Points:

- Nearly three quarters of patients aged >50y starting peritoneal dialysis need help with treatment-related tasks.
- The degree of assistance for peritoneal dialysis-related tasks does not change over the initial six-months of treatment.
- Information about the ongoing need for assistance with treatment-related tasks should be included in shared decision-making discussions.

Abstract:

Background

Home dialysis therapies such as peritoneal dialysis (PD) offer flexibility and improved wellbeing, particularly for older individuals. However, a substantial proportion require assistance with personal care and healthcare related tasks. We hypothesized that patients and families would require less PD assistance as they became more familiar with PD-related tasks. The study objective was to assess whether the nature of, and need for, PD assistance decreased over time.

Methods

Using a multicentred, prospective observational study design, patients aged ≥50 years were recruited from those starting PD. Patients underwent formal evaluation using validated components of a Comprehensive Geriatric Assessment at baseline, and were followed monthly and administered a questionnaire about the need for assistance with PD-related tasks.
Results

A total of 111 patients (age 69 ± 10 years, 68% male, 56% diabetic) were followed for a total of 609 patient-months. Of those who needed help, 40% had help from a family member and 33% were helped by nurses. Both the quantity and nature of help received by patients remained generally stable throughout follow-up, and did not vary according to age, frailty, functional dependence or cognitive impairment (p=0.93). The proportion of patients needing help varied widely across the 13 different tasks, but appeared relatively stable across time. The paid/unpaid caregiver ratio for the different tasks did not change over time.

Conclusion

Older patients initiating PD, in the outpatient setting, have a high need for assistance with PD-related tasks which appears to persist over the initial 6-month period.
Introduction:

Home dialysis therapies such as peritoneal dialysis (PD) offer flexibility, symptom-control and improved wellbeing, particularly for older individuals\(^1\)–\(^5\). Until recently, home dialysis was largely performed by the patients themselves, in their own home environment. Assisted PD has proved to be an efficient and safe modality\(^6\). Patients on PD have variable degrees of functional impairment\(^7\), so over the past decade there has been increased awareness of the need to help patients in managing PD-related tasks at home, to increase access and improve outcomes. Consequently, several models of care have emerged across the world\(^3,8\)–\(^10\) and patients often receive support from both paid- and unpaid- caregivers for a number of treatment-related activities. Within Ontario, the healthcare funding system includes nurse-assisted PD. We previously found that almost half of those patients who initiate dialysis with baseline evidence of frailty, functional decline or cognitive impairment require assistance during the first month of treatment for several tasks associated with PD\(^11\). In this study, we sought to follow up these patients’ needs for assistance over time. We hypothesized, based on our understanding of the clinical trajectory of patients initiating dialysis\(^12\), that several individuals would become more able to independently perform PD-related tasks, while others would require more support over time.
Methods:

Recruitment of patients and baseline assessments have been previously described in detail\textsuperscript{11}. In brief, all patients, aged 50 years or more, initiating peritoneal dialysis (PD) between December 2012 and March 2014, at one of three Ontario centres were approached for participation. Patients were eligible if they were planning to undergo routine PD in their own home environment, as opposed to a nursing home or long-term care. Informed consent was obtained as per research ethics guidelines. Participants were asked to identify individuals who supported them and may potentially assist with their dialysis care. Permission was sought to contact caregivers directly. Patients (or caregivers) were contacted monthly over a period of 6 months and asked, using a structured questionnaire, about what assistance was being given for each of 13 tasks\textsuperscript{11}. As in the previous study, tasks included core PD activities (handwashing; exit site care; assessment of blood pressure and weight; documentation; bag selection; lifting bags; connecting and disconnecting; discarding materials safely and troubleshooting) and instrumental PD activities (ordering supplies; organizing and managing clinic appointments; organizing and managing medications and adding medications to dialysate). For the purposes of the study, we defined assistance as having any form of help for the specific task, including verbal prompting, to ensure the task was being done correctly. Respondents were also asked how much time, in minutes, help was received on an average day, to assess if the amount of time help was needed changed through follow up. For those with longer hospitalization periods (>2 weeks), patients were considered to be receiving full PD assistance for all 13 tasks.
We categorized patients as receiving help if they answered “sometimes”, “often” or “always” (as compared to “rarely” or “never”) when asked if they received help for each activity. Details of who most commonly provided the assistance were categorized, for each task, into two groups: friend/family member (abbreviated to “family”); or help received from a paid caregiver or nurse (abbreviated to “nurse”).

Statistical methods:

Demographic data were analyzed and reported descriptively, using percentages for categorical variables and means (with standard deviations [SD]) or medians (with interquartile ranges [IQR]) as appropriate for continuous variables. Imputation was performed (n= 35 values) using the last observation carried forward methodology for patients who were temporarily unreachable but otherwise had stable results [excluding those censored because of death, transplant, temporary transfer to hemodialysis (HD), or transferred out of center]. For values that were missing in the first follow up month, the value collected from the second month of follow up was used. Imputation on a second time point was not performed if data were missing on more than two consecutive time points. Although this method of deterministically filling in missing data is not generally recommended, the stability of outcomes over time within the patient was felt to give good approximation to model-based imputation.

Trends over time were assessed by summarizing the number of the 13 tasks on which patients required help at each time point. Help received was categorized as none (help with no tasks), minimal (help with 1-4 tasks), moderate (help with 5-9 tasks) or significant (help with 10-13).
Changes in this grouped ordinal variable (none, minimal, moderate or significant) were assessed using a mixed effects proportional odds model (using the package mixor,\textsuperscript{13} which included a random effect for patient, and fixed effects for time). Both summary plots and data analysis used the same data sets for trend analysis, patients that were temporarily off PD, hospitalized or switched to HD at the time of assessment did not contribute data. Odds ratios from this model estimate whether there is a change in the level of help at a follow-up time compared to baseline. A Wald test was used to assess the overall effect of time. Analyses were done using R version 4.0.2 (\textit{R Core Team [2020], Vienna}, \url{https://www.R-project.org/}); a statistical significance threshold of 0.05 was applied.

Results:

Demographic details of the participating patients have been previously reported\textsuperscript{11}. Of 143 eligible patients 121 agreed to participate. Of the initial 121 participants, only 111 entered the longitudinal study (Figure 1). Nine of the 10 patients excluded from the longitudinal study did not start home peritoneal dialysis and therefore did not enter the longitudinal follow up study (1 renal recovery, 7 early technique failure & permanent switch to HD, 1 hospitalized for the full 6-month study period). One participant was unreachable throughout the study period. This patient was maintained in the home setting on peritoneal dialysis but was living in Europe and therefore not contactable.
Longitudinal data were collected for 111 patients to a total of 609 patient months. Of those who contributed longitudinal data, 68% were male with a mean age of 68.9 ± 10.2 years (Table 1). A total of 16/111 (14%) patients ended follow-up prior to completion of the planned follow-up period because of death (n=4), transplantation (n=3), permanent transfer to hemodialysis (n=9), or because the patient transferred to another center (n=1). An additional 2 patients withdrew study consent, and one had renal recovery and discontinued dialysis therapy.

Complete information for all 6 months was available for 57 (51%) participants while a further 34 (31%) had at least 4 follow up assessments. Complete data were available for 536/609 (88%) assessments. Twenty-five assessments were missing in 14 patients as they were hospitalized at the planned time of assessments. Study information was not collected for a further 48 study timepoints because patients were not performing PD at the time of assessment (n=10) or not available for assessment (n=38).

The number of tasks for which patients received help, either from family or nurse, remained stable from month 1 through month 6 for the majority of patients (Figure 2). No differences were seen in the stability of help received over time, for patients identified at baseline as having cognitive impairment, frailty, and/or functional decline (Figure 3 and 4). An average of 73% of patients received help for at least one task during the study period, of whom 40% had help from a family member and 33% by nurses (Figure 5). As previously noted, the amount of help needed was variable among the 13 different tasks, but the proportions of patients receiving help for each task remained relatively stable across time (Figure 2). Overall, patients
received more help with tasks such as lifting bags (55%), ordering and discarding supplies (54% and 54% respectively) and adding medication to the bags when required (53%). Help was least often required for handwashing (overall 7%) and medication management (23.5%). Nursing help was more commonly required for tasks such as adding medications to the bags, cycler set up, and ordering supplies (Figure 2).

Results of the ordinal model reporting trends over time, showed little evidence of change between categories (p=0.93). A total of 6 (5.7%) patients had a change in assistance of more than 2 categories, and 4 (3.8%) changed from the highest (significant assistance) to the lowest (mild assistance) category over their follow-up (Figure 6). The odds ratios representing the change between month 1 and each other month were all close to 1, and ranged from a minimum of 0.88 (i.e., a slight decrease in need for assistance) at months 2 and 6 to a maximum of 1.08 at month 3. The time spent receiving assistance remained stable over the follow up period, with the median per-patient time being 17 minutes per day (IQR 2-47 minutes per day), p=0.62).
Discussion:

In this longitudinal study we observed that there was a relatively stable trajectory in the degree of PD-related assistance required by patients, regardless of age, frailty, functional, or cognitive impairment, over the initial 6-month period after starting PD. Similarly, assistance required for all 13 core and instrumental PD-related tasks appeared to be stable over time. We observed that the need for assistance depended on the task being performed, and that nurses were more likely to help with specific tasks such as adding medication to PD bags, cycler set up and handwashing. Assistance, in our population, was equally often provided by family members as by paid caregivers, and only in rare cases did the responsibility for providing help with one particular task transfer of from one to the other (data available on request).

Our data are important on several fronts. For families and caregivers, these data provide information around what the commitment and care burden is likely to be after dialysis initiation. In the true spirit of advanced care planning, this allows for more realistic expectations for the patient and may help set caregiver expectations and mitigate any negative impact on caregivers’ quality of life. For healthcare practitioners, these data allow improved future planning, robust budgeting and staff training in accordance with regional differences in the demographics of patients initiating onto peritoneal dialysis, particularly those related to functional dependence, cognitive impairment or frailty. This information can complement current planning and inform new policies in different regions trying to expand home-based therapies.\textsuperscript{14}.
One of the main limitations of our study is that data were collected only within three programs, limited to Ontario, Canada, where health care is provided through a socialized universal healthcare system to all citizens and the government finances nursing support for PD. In Ontario, assistance is provided at the discretion of the PD program and community home care services. There are no strict criteria or standards for re-evaluation intervals. This model applies across much of Canada but does not directly translate across other regions and countries of the world. To mitigate this, where possible, we included all patients aged 50 years or more at the time of starting dialysis and recruited widely across large units in Ontario. The use of protocols that measured a number of aspects of geriatric functioning provide detailed description of our patients at baseline, potentially allowing more meaningful comparisons across the populations in different countries and regions.

Our data only partly explain why patients need PD-assistance and what factors prevent their need from reducing over time as we had initially expected. Our observation, for example, that there is incomplete concordance between the presence of frailty, functional or cognitive impairment and assistance emphasizes how the individual clinical scenario is important. Impairments, both physical and cognitive, do not always translate in practice into disability and individuals can continue to function in their own environment despite noticeable impairments with the right supports and strategies\textsuperscript{15}. We anticipated, and did not observe, a decrease in need for assistance based on previous studies\textsuperscript{12} and the expectation that patients would have
increased independence with skill acquisition and mastery over time. We speculate several other reasons may also be at play. Data in the hemodialysis literature have shown little improvement in overall functional wellbeing over time, and therefore it may be unrealistic to expect patients’ wellbeing to improve sufficiently with PD such that they are well enough to assume more PD-related tasks. It is possible that patients, and/or their caregivers, become acclimatized to receiving and giving assistance, and caregiver-patient pairs align their expectations with a ‘sick-role’ model. Also likely is high risk that patients starting onto PD accumulate new or worsening comorbid conditions that leads to a decline in their personal functioning and their ability to partake in daily activities. Previous findings about PD-assistance vary and are incomplete. A pilot PD assistance program from British Columbia included both respite and long-term PD assistance. Of those offered temporary respite PD assistance, 73% returned to unassisted PD within 3 months. In contrast, the majority who started onto long-term PD-assistance remained on assisted PD at the end of follow up, with only 5 out of 53 having transitioned to unassisted PD after 12 months. Recent data from Ontario Renal Network show that approximately 25% of all prevalent PD patients in Ontario receive paid assistance at any given time point and 35% have received it at some time during the prior 12 months. Although differences in study methodology, the patient or caregiver perspective, population and data sources, may contribute to the observed variations, we believe that the
results presented in this study do accurately estimate the needs over time particularly as data were collected directly from patient or caregiver sources. Nevertheless, this should continue to be an active area of research.

In summary, we have identified that a substantial number of patients starting PD when aged 50 years or more require assistance for PD related tasks and this proportion declines little over the initial six-months. It emphasizes the importance of starting discussions early, introducing advance care plans, goals and most importantly expectations as patients approach dialysis initiation.
Disclosures:
M. Oliver reports Ownership Interest: Sole owner of Oliver Medical Management Inc. which is a private corporation that licenses the Dialysis Measurement Analysis and Reporting (DMAR) software system; Research Funding: Baxter Healthcare and Medtronic have provided funding support to create a PD catheter registry for the International Society of Peritoneal Dialysis; Honoraria: Janssen, Amgen, Baxter Healthcare; Patents and Inventions: Oliver Medical Management Inc. is co-owner of a Canadian Patent for DMAR systems. A. Jain reports Research Funding: Baxter Healthcare; Honoraria: Baxter Healthcare, AWAK Technologies. S. Jassal reports Honoraria: Otsuka (Apr2020); Other Interests/Relationships: Sanofi, Janssen Ortho & Alexion provide unrestricted educational grants for educational meetings that I participate in. All remaining authors have nothing to disclose.

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Author Contributions:
J. I. Fonseca-Correa: Investigation; Writing - original draft; Writing - review and editing
J. Farragher: Data curation; Investigation; Project administration; Writing - review and editing
G. Tomlinson: Formal analysis; Writing - review and editing
M. Oliver: Conceptualization; Funding acquisition; Methodology; Writing - review and editing
A. Jain: Investigation; Writing - review and editing
S. Flanagan: Data curation; Writing - review and editing
K. Koyle: Data curation; Writing - review and editing
S. V. Jassal: Conceptualization; Data curation; Formal analysis; Funding acquisition; Methodology; Project administration; Supervision; Writing – review and editing


Table 1: Table showing demographic details of study population at time of dialysis initiation

<table>
<thead>
<tr>
<th></th>
<th>Total (n=111)</th>
<th>Any assistance (n=82)</th>
<th>No assistance (n=29)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>68.9 ± 10.2</td>
<td>69.8 ± 10.1</td>
<td>66.28 ± 10.3</td>
<td>0.10</td>
</tr>
<tr>
<td>Male</td>
<td>75 (68%)</td>
<td>54 (66%)</td>
<td>21 (72.4%)</td>
<td>0.51</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full-time</td>
<td>12 (11%)</td>
<td>4 (5%)</td>
<td>8 (28%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Part-time</td>
<td>9 (8%)</td>
<td>6 (7%)</td>
<td>3 (10%)</td>
<td>0.60</td>
</tr>
<tr>
<td>Not employed</td>
<td>87 (78%)</td>
<td>69 (84%)</td>
<td>18 (62%)</td>
<td>0.01</td>
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<tr>
<td>Unknown</td>
<td>3 (3%)</td>
<td>3 (4%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not complete grade school</td>
<td>14 (13%)</td>
<td>13 (16%)</td>
<td>1 (3%)</td>
<td>0.08</td>
</tr>
<tr>
<td>Grade school</td>
<td>24 (22%)</td>
<td>21 (26%)</td>
<td>3 (10%)</td>
<td>0.08</td>
</tr>
<tr>
<td>High school</td>
<td>19 (17%)</td>
<td>12 (15%)</td>
<td>7 (24%)</td>
<td>0.24</td>
</tr>
<tr>
<td>College/trade</td>
<td>22 (20%)</td>
<td>13 (16%)</td>
<td>9 (31%)</td>
<td>0.07</td>
</tr>
<tr>
<td>University degree</td>
<td>29 (26%)</td>
<td>20 (24%)</td>
<td>9 (31%)</td>
<td>0.48</td>
</tr>
<tr>
<td>Unknown</td>
<td>3 (3%)</td>
<td>3 (4%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Lives alone</td>
<td>22 (20%) (n=108)</td>
<td>12 (15%) (n=79)</td>
<td>10 (35%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Started dialysis as inpatient</td>
<td>18 (16%)</td>
<td>13 (16%)</td>
<td>5 (17%)</td>
<td>0.86</td>
</tr>
<tr>
<td>Transferred from HD</td>
<td>23 (21%)</td>
<td>18 (22%)</td>
<td>5 (17%)</td>
<td>0.59</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>62 (56%)</td>
<td>54 (66%)</td>
<td>8 (27%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>25 (23%)</td>
<td>20 (24%)</td>
<td>5 (17%)</td>
<td>0.42</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>25 (23%)</td>
<td>21 (26%)</td>
<td>4 (14%)</td>
<td>0.19</td>
</tr>
<tr>
<td>Other cardiac disease</td>
<td>46 (41%)</td>
<td>33 (40%)</td>
<td>13 (45%)</td>
<td>0.66</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>11 (10%)</td>
<td>9 (11%)</td>
<td>2 (7%)</td>
<td>0.52</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>9 (8%)</td>
<td>9 (11%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
<tr>
<td>Cancer</td>
<td>15 (14%)</td>
<td>10 (12%)</td>
<td>5 (17%)</td>
<td>0.46</td>
</tr>
<tr>
<td>Gastrointestinal bleed</td>
<td>5 (5%)</td>
<td>4 (5%)</td>
<td>1 (3%)</td>
<td>0.75</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>8 (7%)</td>
<td>6 (7.3%)</td>
<td>2 (7%)</td>
<td>0.94</td>
</tr>
<tr>
<td>Laboratory values</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine, mg/dL (median, IQR)</td>
<td>5.67 (5.09 – 8.81)</td>
<td>6.39 (4.94 – 7.44)</td>
<td>8.25 (6.04 – 11.00)</td>
<td>0.005</td>
</tr>
<tr>
<td>Urea, mg/dL</td>
<td>78.4 ± 26 (n=108)</td>
<td>77.9 ± 26.8 (n=78)</td>
<td>89.4 ± 22.7</td>
<td>0.045</td>
</tr>
<tr>
<td>Albumin, g/L</td>
<td>3.5 ±0.5 (n=108)</td>
<td>3.49 ± 0.5 (n=79)</td>
<td>3.57 ± 0.53</td>
<td>0.43</td>
</tr>
<tr>
<td>Hemoglobin, g/L</td>
<td>9.8 ± 1.42</td>
<td>9.78 ± 1.38</td>
<td>9.93 ± 1.58</td>
<td>0.61</td>
</tr>
<tr>
<td>Disabilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional</td>
<td>72 (66%) (n=110)</td>
<td>59 (72.8%) (n=81)</td>
<td>13 (45%)</td>
<td>0.006</td>
</tr>
<tr>
<td>Cognitive</td>
<td>63 (59%) (n=106)</td>
<td>55 (71.4%) (n=77)</td>
<td>8 (28%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Frailty</td>
<td>65 (64%) (n=101)</td>
<td>50 (68.5%) (n=73)</td>
<td>15 (54%) (n=28)</td>
<td>0.16</td>
</tr>
<tr>
<td>Number of tasks needing assistance (median; IQR)</td>
<td>-</td>
<td>6.5 (3-10)</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: HD, hemodialysis; IQR, interquartile range; N/A, not applicable
FIGURE LEGENDS:

Figure 1.
Study flow diagram.

Figure 2.
Figure illustrating proportion of patients receiving help with each of the tasks over time. Each column represents one task, over the 6 month period. Care may have been provided by a paid caregiver (dark grey) or a family member (mid grey). N/A represents patients where the task was not applicable (i.e. adding medication to PD bags or using a cycler). Sample sizes for months one through six were 109, 104, 101, 93, and 91 subjects, respectively.

Figure 3.
Figure showing each individual patient requirement for PD assistance over time. Panel A represents all patients, arranged by initial category of assistance received, panel B represents all patients arranged by age group. Each horizontal line represents one individual followed over the study period. The degree of shading represents the number of tasks for which assistance was required. Patients who were temporarily off PD, transferred to HD or censored had data missing and are shown in white. Age bands included: 50-59 years (n=20), 60-69 years (n=40), 70-79 years (n=30), ≥80 years (n=21).

Figure 4.
Figure illustrating change in PD-assistance received by study patients over time, categorized into four groups according to baseline assessment results for a) frailty (n=65/101), b) functional impairment (n=72/110), c) cognitive impairment (n=63/106), or d) any of the three impairments (n=99/111). Each horizontal line represents one individual followed over the study period.
Figure 5.
Figure showing proportion of patients receiving help from a nurse (light grey) or family member (dark grey) for one or more PD-related activities over the 6-month study period. The black shaded area represents the proportion of patients independent with all tasks.

Figure 6
Alluvial plot showing participants’ trends in degree of assistance over time.
Figure 1

143 subjects started on PD (Dec. 2012 – Mar. 2014)

121 agreed to participate in baseline assessment

Excluded: 10
- Early PD failure: 7
- Renal recovery: 1
- Not reachable or hospitalized: 2

111 for longitudinal follow up

Censored: 20
- Death: 4
- Transplantation: 3
- Transfer to HD: 9
- Centre transfer: 1
- Withdrew consent: 2
- Renal recovery: 1

91 completed 6-month follow up
Figure 3

A) All patients

B) All patients, by age group

Legend:
- No assistance required
- Minimal assistance required (1-4 tasks)
- Moderate assistance required (5-9 tasks)
- Significant assistance required (>10 tasks)
- Data unavailable (see text)
Figure 4

A) Frailty

B) Functional impairment

C) Cognitive impairment

D) Frailty, Cognitive, and/or Functional Impairment

Legend:
- No assistance required
- Minimal assistance required (1-4 tasks)
- Moderate assistance required (5-9 tasks)
- Significant assistance required (>10 tasks)
- Data unavailable (see text)
Figure 6