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Depression in Visual Impairment Trial (DEPVIT): A Randomized Clinical Trial of Depression Treatments in People With Low Vision

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Purpose. The purpose of this study was to compare two interventions for depression, problem solving treatment (PST) and referral to the patient’s physician, with a waiting-list control group in people with sight loss and depressive symptoms.

Methods. This was an assessor-masked, exploratory, multicenter, randomized clinical trial, with concurrent economic analysis. Of 1008 consecutive attendees at 14 low-vision rehabilitation centers in Britain, 43% (n = 430) screened positive for depressive symptoms on the Geriatric Depression Scale and 85 of these attendees participated in the trial. Eligible participants were randomized in the ratio 1:1:1 to PST, referral to their physician, or a waiting-list control arm. PST is a manualized talking intervention delivered by a trained therapist who teaches people over six to eight sessions to implement a seven-step method for solving their problems. Referral to the physician involved sending a referral letter to the person’s physician, encouraging him or her to consider treatment according to the stepped care protocol recommended by the U.K.'s National Institute of Health and Care Excellence. The primary outcome was change in depressive symptoms (6 months after baseline) as determined by the Beck Depression Inventory.

Results. At 6 months, Beck Depression Inventory scores reduced by 1.05 (SD 8.85), 2.11 (SD 7.60), and 2.68 (SD 7.93) in the waiting-list control, referral, and PST arms, respectively. The cost per patient of the PST intervention was £1176 in Wales and £1296 in London.

Conclusions. Depressive symptoms improved most in the PST group and least in the control group. However, the change was small and the uncertainty of the measurements relatively large.

Keywords: low vision, depression, clinical trial, mental health, intervention

A growing body of evidence suggests that low vision is associated with depression. Results from several studies in North America suggest that the prevalence of depression and depressive symptoms in those accessing visual rehabilitation centers ranges from 22% to 38%. Untreated depression has a profound negative impact on quality of life and reduces life expectancy. What is less clear, however, is how to treat the depressive symptoms in this vulnerable group.

In otherwise healthy adults, about 50% of those who receive psychological treatments or antidepressants recover fully. However, the effects of depression treatment in people with chronic health conditions are somewhat less clear. For example, a recent meta-analysis of psychological interventions for depression in people with coronary heart disease concluded that although psychological treatments work, the effects are only small (typical effect size 0.3). A myriad of psychological interventions have been developed for depression, but perhaps the best known and most useful approaches in the context of those with chronic health problems are cognitive behavioral therapy (CBT), behavioral
Depression Treatments in People With Low Vision

Antidepressant drugs are not recommended for the treatment of subthreshold depressive symptoms or mild depression in people with chronic health problems. However, they may be of value in those with long-standing subthreshold symptoms or a past history of moderate or severe depression.7

In those with sight problems and depression, there is some evidence that psychological treatments for depression work. For example, in a clinical trial comparing PST to usual care in people with age-related macular degeneration (AMD), PST halved the incidence of a depressive disorder at 2 months, although the effect had reduced by 6 months.14 Recently, the Low Vision Depression Prevention Trial, which studied AMD patients with subthreshold depressive symptoms, showed that BA combined with occupational therapy halved the incidence of depressive disorders at 4 months.15

In the United States, access to mental health care services has been improved by the Affordable Care Act and expansion of Medicaid, particularly for those most in need.16,17 In Britain, mental health care is provided by the National Health Service (NHS) and accessed via the patient’s physician. Within the NHS, the treatment of people with chronic health problems and depressive symptoms is supposed to adhere to the detailed guidelines published by the National Institute for Health and Care Excellence (NICE).7

To obtain data on the effectiveness of a manualized PST intervention and a pragmatic referral to the physician to invoke the NHS’s stepped care approach to depression treatment, we established the Depression in Visual Impairment Trial (DEPVIT).

DEPVIT sought to establish the prevalence of significant depressive symptoms in people attending visual rehabilitation centers in Britain and undertake an exploratory trial to find out if PST or physician referral were effective at reducing depression in people with impaired vision and significant depressive symptoms.

METHODS

The methods for DEPVIT have been previously described in detail.18 In brief, the study was a multicenter, individually randomized, parallel group, exploratory clinical trial. Two interventions, PST and physician referral, were evaluated alongside a waiting-list control. All participants had a follow-up low-vision appointment 6 weeks after the initial low-vision assessment.

Eligible participants were adults (aged 18 and older) attending participating low-vision centers (two hospitals in London and 12 primary care clinics in South Wales) who scored ≥ 6 on the Geriatric Depression Scale (GDS-15).19 To ensure the applicability of the results to the target population, exclusion criteria were kept to a minimum. We excluded those who (1) had a low-vision assessment within the previous 12 months, (2) were referred to the clinic in error, (3) were already receiving depression treatment, (4) were unable to understand English, (5) were unable to use the telephone as a result of poor hearing, (6) had a severe medical illness that would preclude participation, (7) reported suicidal ideation, (8) were outside the catchment area, or (9) screened positive for significant cognitive/memory problems. The trial followed the tenets of the Declaration of Helsinki and was approved by the NHS National Research Ethics Service (11/WA/0014) and an independent trial steering committee provided study oversight. The trial was registered prior to recruitment of the first participant (ISRCTN registry no. 46924140).

The PST implemented in this trial was a brief manualized cognitive behavioral therapy based on that used by Rovner et al.14 Trained psychological therapists worked with participants on an individual basis in their own home or at one of the research centers to teach them a seven-step method for approaching and solving their problems. The only differences between the intervention studied here and that in the original publication were that the intervention also included large-print self-help materials on depression and a list of vision-related organizations. The optometrists providing the low-vision assessment also shared the patient’s treatment plan with the therapist via a brief report so that the therapist could help the patient implement the optometrist’s recommendations via the PST framework if these were problems that the participant wanted to address.

To ensure standardization, all three therapists delivering PST undertook rigorous training and certification before seeing trial participants. All PST sessions were recorded and a random sample was reviewed for fidelity purposes.

The referral condition consisted of a standardized letter (letter 1) sent to the participant’s physician within 2 weeks of randomization. It informed the physician that their patient had screened positive for significant depressive symptoms and asked them to offer treatment according to NICE guidelines.7 The letter was sent by the research team but appeared to come from the participant’s optometrist. This strategy was used to mask the fact that the participant was in a research study, which may have altered the physicians’ behavior. Physicians were informed about their patients’ participation in this trial 6 months after randomization and asked for information about any depression treatments offered to the patient during this period. This was a pragmatic intervention that aimed to determine the impact of a typical referral, not specifically the stepped care approach to depression treatment recommended by the NICE guidelines. The recommended stepped care approach provides a framework in which to provide services where the least intrusive, most effective intervention is provided first. If patients do not respond to the intervention offered initially, the treatment is stepped up to the next level.

Participants in the waiting-list control arm received no intervention other than the 6-week follow-up low-vision assessment.

Any participant who reported severe symptoms (a Beck Depression Inventory [BDI-II] score of 29 or more) at baseline or follow-up was referred to their physician for a medication review using a standardized medication referral letter (letter 2).

The primary outcome was change in depressive symptoms from baseline to 6 months as measured by the BDI-II. Secondary outcomes included (1) change in BDI-II baseline to 3 months and 3 to 6 months; (2) change in visual disability since baseline interview, as measured by the seven-item National Eye Institute Visual Function Questionnaire (NEI VFQ); (3) change in near-visual function as measured using the near-vision subscale of the Visual Function Questionnaire (VFQ-48); (4) change in generic health-related quality-of-life as measured by the EuroQol five dimensions questionnaire (EQ-5D); and (5) the proportion of participants screening positive for depression at 6 months using GDS-15.

The randomization sequence was created by the senior data manager using permuted blocks of varying sizes and was concealed from the optometrists enrolling participants and the researchers who obtained the outcomes via telephone interview. The chief investigator (CI) consulted the allocation sequence and assigned participants to the next available allocation.

As a result of the nature of the interventions, participants were aware of their treatment assignment. The therapists were aware which participants were assigned to PST; the GPs were unaware that the participant was in a trial so as not to bias their actions, and the optometrists were masked to treatment.
Table 1 describes the demographic characteristics by treatment assignment.

Table 2 shows the primary and secondary outcomes by treatment group. At 6 months, depressive symptoms had reduced in all three arms. In the waiting-list control arm, depressive symptoms were reduced by $-1.05$ (95% CI $-4.33$ to $2.23$), in the referral arm by $-2.11$ (95% CI $-4.98$ to $0.76$), and in the PST arm by $-2.68$ (95% CI $-6.00$ to $0.63$). In all cases, the 95% CI spanned zero, suggesting that change was not significant at the 5% level.

Post hoc analyses suggest that depressive symptoms reduced most in those with moderate to severe depressive symptoms at baseline, that is, a BDII $>20$. Specifically, in the waiting-list control, referral, and PST arms, depressive symptoms reduced by $-2.4$, $-5.0$, and $-6.1$, respectively, in those with moderate to severe depression at baseline, and by only $0.3$, $2.3$, and $-0.3$, respectively, in those with mild or minimal symptoms at baseline.

At 6 months, the proportion of people still screening positive for depression according to the GDS-15 had decreased to $33.3\%$ (95% CI 15.5–51.1), $38.5\%$ (95% CI 19.8–57.2), and $40.9\%$ (95% CI 20.4–61.5) of those in the waiting-list, referral, and PST arms, respectively.

Table 3 summarizes the action taken by physicians in response to the referral letters. Letter 1 was for those in the referral arm. Letter 2 was used to refer all those who had severe depressive symptoms (BDII $>29$). Of the physicians who responded (32 of 36), approximately 65% indicated that they had at least met the patient, and 25% of patients were offered antidepressants.

On average, South Wales participants received 6.15 PST sessions (SD 1.21), lasting an average of 1.37 hours (SD 0.41). Allowing for travel time, the total estimated therapist time was $3.48$ hours per session (SD 1.12), giving an average cost per session of £196 in Wales and £216 in London.

Table 4 summarizes the health and social care service use costs in each study group for 6 months. The total health and social care costs, excluding the cost of the interventions, incurred by those in the waiting-list, referral, and PST arms of the trial during the 6-month study period were £1444 ($1941$), £1362 (SD £1814), and £962 (SD £1051), respectively.

Of the PST recordings, 16% were randomly selected and reviewed by D.S. using the PST Therapist Adherence and Competence Scale to ensure fidelity of the intervention. The therapist in Wales received an average score of 4/5, indicating that the sessions delivered were rated as good. The first therapist in London conducted only four sessions and was not reviewed. The second therapist received an average rating of 3.3/5, indicating that the sessions were satisfactory to good.

The researchers were inadvertently unmasked by comments made by participants during 6.8% of interviews, and the researcher guessed the allocation arm correctly in another 4.1% of cases, that is, only a little higher than by chance alone.

Participants in the waiting-list control group were asked to refrain from consulting their physician for depression until after the 6-month interview. Despite this, two participants, one in Wales and one in London, received depression treatment from their physicians by 6 months.

Two adverse events were reported, and one was considered to be related to their prescribed treatment: the participant experienced dizziness and fell after taking newly prescribed antidepressant medication. Ten serious adverse events were reported during the trial, but none were related to the trial.

One participant in the control group reported suicidal ideation during the 3-month outcome assessment. As per protocol, he was withdrawn from the trial and urgently referred to his physician.
DISCUSSION

Those randomized to receive PST experienced the greatest reduction in depressive symptoms, and those in the waiting list the least, but the results were not compelling. The study suggests that neither active intervention would reduce depression by the minimal clinically important difference, although both did appear better than current standard care. Working on the basis of the primary outcome measure results alone, power calculations suggest that we would need a sample size of > 400 participants per arm to be reasonably confident of demonstrating a statistically significant difference between participants on the waiting list and those in receipt of PST.

So why was PST not more effective? One possibility is that this intervention was not well matched with the sample studied. The inclusion criteria were wide ranging; DEPVIT included people with mild, moderate, and severe depressive symptoms. A post hoc analysis suggested that those with
results are in logits, but the scales work in different directions. More positive scores on the LV VFQ 48 indicate greater ability. More positive scores mean change in near reading ability (Near Vision subscale of the LV VFQ-48), and mean change in visual disability (seven-item NEI-VFQ). Both sets of scores on the seven-item NEI-VFQ indicate greater disability; mean change in health status (EQ-5D).

Referral letter 1 was a carefully crafted letter and was the intervention. It represented the most likely course of action if we asked both the participants and their physicians about any treatments received. Of the 36 referrals to the physicians, we were unable to get a response from four physicians, and seven said that they did not receive the referral letter. Clearly, although the physician’s contact details were cross checked with the practice website at the time the referral letter was sent, communication breakdown between the referral center and the physician is a distinct possibility. A phone call to check

### Table 2. Primary and Secondary Outcomes

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Waiting List</th>
<th>Referral</th>
<th>PST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depressive symptoms (BDI-II)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean baseline value (SD)</td>
<td>20.30 (10.33)</td>
<td>21.06 (7.61)</td>
<td>19.04 (10.62)</td>
</tr>
<tr>
<td>Change from baseline to 3 months (SD)</td>
<td>−2.85 (10.38)</td>
<td>−1.14 (8.49)</td>
<td>−2.27 (5.81)</td>
</tr>
<tr>
<td>Change from baseline to 6 months (SD)</td>
<td>−1.05 (8.85)</td>
<td>−2.11 (7.60)</td>
<td>−2.68 (7.94)</td>
</tr>
<tr>
<td>Screening positive at 6 months (GDS-15)</td>
<td>33.3%</td>
<td>38.5%</td>
<td>40.9%</td>
</tr>
<tr>
<td>Reading ability (LV VFQ-48)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean baseline value (SD)</td>
<td>−1.20 (1.64)</td>
<td>−1.02 (1.96)</td>
<td>−0.83 (1.52)</td>
</tr>
<tr>
<td>Change from baseline to 3 months (SD)</td>
<td>0.17 (1.35)</td>
<td>−0.05 (1.05)</td>
<td>−0.10 (1.78)</td>
</tr>
<tr>
<td>Change from baseline to 6 months (SD)</td>
<td>−0.09 (1.79)</td>
<td>−0.08 (1.17)</td>
<td>−0.09 (1.67)</td>
</tr>
<tr>
<td>Visual disability (seven-item NEI-VFQ)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean baseline value (SD)</td>
<td>0.90 (1.35)</td>
<td>0.43 (1.88)</td>
<td>0.52 (1.39)</td>
</tr>
<tr>
<td>Change from baseline to 3 months (SD)</td>
<td>−0.25 (1.26)</td>
<td>0.19 (1.21)</td>
<td>0.13 (1.58)</td>
</tr>
<tr>
<td>Change from baseline to 6 months (SD)</td>
<td>−0.34 (1.68)</td>
<td>0.22 (0.99)</td>
<td>0.35 (1.51)</td>
</tr>
<tr>
<td>Health status (EQ-5D)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean baseline value (SD)</td>
<td>0.47 (0.32)</td>
<td>0.43 (0.40)</td>
<td>0.43 (0.34)</td>
</tr>
<tr>
<td>Change from baseline to 3 months (SD)</td>
<td>0.02 (0.26)</td>
<td>0.03 (0.25)</td>
<td>0.07 (0.23)</td>
</tr>
<tr>
<td>Change from baseline to 6 months (SD)</td>
<td>0.02 (0.37)</td>
<td>−0.34 (0.29)</td>
<td>−0.07 (0.29)</td>
</tr>
</tbody>
</table>

Mean change in depressive symptoms at 3 and 6 months, proportion screening positive for depression at 6 months (GDS-15 score of 6 or more), mean change in near reading ability (Near Vision subscale of the LV VFQ-48), and mean change in visual disability (seven-item NEI-VFQ). Both sets of results are in logits, but the scales work in different directions. More positive scores on the LV VFQ 48 indicate greater ability. More positive scores on the seven-item NEI-VFQ indicate greater disability; mean change in health status (EQ-5D).

### Table 3. Physician’s Responses to Referral Letters

<table>
<thead>
<tr>
<th>Action Taken by Physician</th>
<th>Referral Letter 1, % (n)</th>
<th>Referral Letter 2, % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient offered medication</td>
<td>12.9 (4)</td>
<td>60 (3)</td>
</tr>
<tr>
<td>Patient offered other</td>
<td>19.4 (6)</td>
<td>20 (1)</td>
</tr>
<tr>
<td>Patient offered medication</td>
<td>12.9 (4)</td>
<td></td>
</tr>
<tr>
<td>and other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appointment with physician but no treatment</td>
<td>9.7 (3)</td>
<td></td>
</tr>
<tr>
<td>Offered appointment but patient declined</td>
<td>3.2 (1)</td>
<td>20 (1)</td>
</tr>
<tr>
<td>No appointment</td>
<td>6.5 (2)</td>
<td></td>
</tr>
<tr>
<td>Did not receive letter</td>
<td>22.6 (7)</td>
<td></td>
</tr>
<tr>
<td>No response from physician</td>
<td>12.9 (4)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>100 (31)</td>
<td>100 (5)</td>
</tr>
</tbody>
</table>

Two types of letters were sent to physicians during the trial. Referral letter 1 was a carefully crafted letter and was the intervention in the referral arm of the trial. The trial was stratified for severe/not severe depressive symptoms (BDI-II score of 29 or more). For all of those with severe depressive symptoms in any arm of the trial, referral letter 2 was sent to the physician. This letter indicated that the patient had severe depressive symptoms and requested a medication review.
if the physician has received the referral letter would be helpful in future studies.

It was not part of our analysis plan to determine what happened to participants offered different interventions by the physician, but it is perhaps noteworthy that 25% of those referred to their physician were offered antidepressants. In DEPVIT, depressive symptoms reduced by 13.2 (SD 6.3) points on the BDI-II in the six people who were offered medication and for whom data were available. Antidepressants are an inexpensive, straightforward, and effective means of reducing depressive symptoms. However, antidepressant use may be associated with side effects such as insomnia, nausea, increased weight gain, drowsiness, and agitation, and the rate of relapse is relatively high.

Assuming that six sessions of PST would be offered to each person on average, the overall costs of this intervention were £1176 in Wales and £1296 in London. Total health and social care service use costs during the 6-month trial period were £400 lower in the PST arm of the trial than in the referral arm and £482 lower in the PST arm than in the control arm. However, although there is some suggestion that PST may reduce costs, when the cost of the PST intervention is added, the total cost of those in the PST arm was greater than in the other arms of the trial.

The relatively high number of serious adverse events and difficulties experienced making appointments to deliver PST during the trial reflects the underlying state of health of the participants. Participants were elderly, and comorbidity was common. Interventions aimed at reducing depression in this patient group, including those delivered via a stepped care approach, should consider the practical difficulties associated with intervention delivery. That some participants found engaging with PST difficult because they claimed not to have offered an uptake decision at the start of chemotherapy is 45%. We provide a description of the prevalence data in another publication. Another significant observation from DEPVIT was that the prevalence of significant depressive symptoms in visual problems suggests that PST may not be appropriate for everyone.

One important finding from the DEPVIT study was that the prevalence of significant depressive symptoms in visual rehabilitation clinics in Britain, at 43%, is among the highest reported anywhere in the world. To put these findings in perspective, other studies using the GDS-15 and the same cut-off point have estimated that the prevalence of significant depressive symptoms in people with a cancer diagnosis about to start chemotherapy is 45%. We provide a description of the prevalence data in another publication.

Another significant observation from DEPVIT was that the response rate was relatively low. That is, the main reason for nonparticipation (n = 345) was refusal (n = 110; 32%). Refusal is a common finding in other trials in this population. For example, in the study by Rovner et al., refusal was the main reason (66%) for nonparticipation, and in the study by van der Za et al., only 914 of 3000 people invited to take part in the study provided written consent. A better understanding of the reasons why people are declining to take part may improve offer of treatment.
The results of this trial add to those of other trials recently published in this research area. For example, van der Aa et al.\textsuperscript{29} showed that a stepped care approach, which comprised watchful waiting, guided self-help based on cognitive-behavioral therapy, problem-solving treatment, and referral to a general practitioner significantly reduced the risk (relative risk 0.63) of a depressive dysthymic and/or anxiety disorder at 24 months.\textsuperscript{29} In another study, a relatively simple, low-intensity psychological intervention known as BA, a treatment that helps people recognize the link between action and mood, often delivered in the person’s own home by an occupational therapist during an 8-week period, was shown to halve the incidence of depressive disorders in people with AMD at 4 months.\textsuperscript{15} In contrast, an 8-week, group-based low-vision self-management program based on cognitive-behavioral approaches and social cognitive theory did not reduce depressive symptoms at 6 months in people with low vision.\textsuperscript{30} However, the people in that study were psychologically normal at baseline. Another well designed clinical trial showed the antidepressant therapy, escitalopram, to be effective at reducing depression in a small group of people with AMD and depression at 4 months.\textsuperscript{31} Collectively, these studies suggest that psychological and pharmacological interventions can be effective in reducing depression in people with low vision. However, comparisons are complicated because of differences in the samples studied, the interventions tested, the follow-up period, the instruments used to measure depression and outcome measures, for example, change in depressive symptoms versus proportions with a depressive disorder. Table 5 summarizes the differences and outcomes of recent clinical trials in this area. Overall, it appears that the psychological interventions studied to date produce a small effect size (0.19 to 0.32) in people with low vision and depressive symptoms. These modest findings are typical of those observed in other chronic health conditions.\textsuperscript{10} The larger effect size (0.67) observed in the small antidepressant trial is consistent with results obtained for those prescribed antidepressants in DEPVIT, but larger studies are needed.\textsuperscript{31}

Taken together, these studies and our own experience of trying to deliver psychological interventions to those with the full spectrum of depressive symptoms (from mild to severe) has led us to believe that screening this high-risk group is vital; although PST may be helpful to some, it is not a panacea, and there may be better low-intensity psychological interventions, such as BA. It is unlikely that one intervention will suit everyone, and hence patients should be offered a range of treatment options tailored to their individual needs and the severity of their depression. The stepped care delivery platform can facilitate the delivery of individualized care and provide long-term benefits.

The strengths of this study include publication of the study protocol before recruitment began, an analysis based on prespecified primary and secondary outcomes, relatively successful masking of the outcome assessors, identification of sources of bias, a minimal set of exclusion criteria, and a large number of consecutive participants originally screened. Limitations of this study included a relatively modest sample size ($n = 85$) and practical difficulties experienced trying to deliver PST per protocol.

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### References


### Table 5. Comparison of Clinical Trials of Depression Treatments in People With Sight Loss

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Baseline Depression</th>
<th>Measure</th>
<th>Intervention</th>
<th>Follow-Up, mo</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rovner et al., 2014\textsuperscript{15}</td>
<td>188</td>
<td>Mild</td>
<td>PHQ-9</td>
<td>Behavioral activation</td>
<td>4</td>
<td>0.32</td>
</tr>
<tr>
<td>Van der Aa et al., 2015\textsuperscript{29}</td>
<td>265</td>
<td>Mild</td>
<td>CES-D</td>
<td>Stepped care</td>
<td>24</td>
<td>0.21</td>
</tr>
<tr>
<td>Brody et al., 2011\textsuperscript{16}</td>
<td>16</td>
<td>Mild/moderate</td>
<td>HAMD-17</td>
<td>Escitalopram</td>
<td>4</td>
<td>0.67</td>
</tr>
<tr>
<td>Rees et al., 2015\textsuperscript{30}</td>
<td>153</td>
<td>Normal</td>
<td>DASS</td>
<td>LVSM</td>
<td>6</td>
<td>0.00</td>
</tr>
<tr>
<td>DEPVIT</td>
<td>85</td>
<td>Moderate</td>
<td>BD-HI</td>
<td>PST</td>
<td>6</td>
<td>0.19</td>
</tr>
</tbody>
</table>


