

Enhancing management of tuberculosis treatment with video directly observed therapy in New York City

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SUMMARY

SETTING: Directly observed therapy (DOT), the standard of care for monitoring patients on treatment for tuberculosis (TB), requires substantial health department resources, and can be inconvenient and disruptive for patients.

OBJECTIVE: To determine whether video technology for remote observation of patients on anti-tuberculosis treatment (VDOT) is as effective as in-person DOT.

DESIGN: Eligible TB patients in New York City were prospectively enrolled in VDOT from September 2013 to September 2014. We compared treatment outcomes and worker output for VDOT and in-person DOT.

RESULTS: Among 390 patients on DOT for the treatment of TB, 61 (16%) were on VDOT and 329 (84%) on in-person DOT. Adherence to scheduled VDOT sessions

was 95% (3292/3455) compared to 91% (32 204/35 442) with in-person DOT ($P < 0.01$). VDOT enabled a DOT worker to observe a maximum of 25 patients per day, similar to DOT workers who observed patients in clinic ($n = 25$), but twice that of DOT workers who observed patients in the community ($n = 12$). Treatment completion with VDOT was similar to that with in-person DOT (96% vs. 97%, $P = 0.63$). The primary problems encountered during VDOT sessions were interruption of video and audio connectivity.

CONCLUSION: Implementation of VDOT resulted in successful anti-tuberculosis treatment outcomes while maximizing health department resources.

KEY WORDS: VDOT; telemedicine; remote monitoring

TREATMENT FOR TUBERCULOSIS (TB) is lengthy, requiring 6–9 months of multiple drugs; however, when treatment is taken as prescribed the cure rate is high.¹ Failure to complete treatment can lead to the development of drug-resistant TB, which is more difficult to treat and can result in continued community transmission and increased morbidity and mortality.^{2,3} To ensure adherence to anti-tuberculosis treatment, the Centers for Disease Control and Prevention and other health agencies recommend directly observed therapy (DOT) as the standard of care for TB patients.^{4,5} DOT involves a trained health care worker observing patients ingest each dose of their medication. Studies show that DOT increases treatment completion, reduces disease recurrence, and prevents the development of drug resistance.^{6–8} During the TB resurgence in the 1990s in the United States, DOT was credited with reducing primary drug resistance from 13% to 7% and acquired drug resistance from 14% to 2% in some areas.⁹

In New York City (NYC), DOT was recognized as being instrumental in curbing the 1990s TB epidemic.¹⁰ The proportion of patients who completed treatment increased from 44% in 1984 to 86% in

2004, concurrent with an increase in the proportion of patients treated under DOT.¹¹ Furthermore, a recent study showed that NYC patients on DOT had a lower risk of delayed and incomplete treatment.¹² Transmission and development of drug-resistant TB also decreased, and the number of TB cases in NYC dropped from 3756 in 1992 to 585 in 2014.¹³ The NYC Department of Health and Mental Hygiene (DOHMH) offers DOT to all patients taking treatment for TB who are not hospitalized or in a prison, treatment facility, or nursing home. DOT is offered at all TB clinics and in the community at locations convenient for the patient, such as home or worksite. NYC DOHMH conducts about 40 000 DOT observations annually.¹³ State-approved NYC hospitals offer DOT to patients in their clinics, and report DOT information to the DOHMH.

DOT requires substantial personnel time, costs for transportation, and vehicle maintenance. In addition, DOT can be inconvenient and disruptive for patients,¹⁴ and ethical and privacy concerns about the use of DOT have been raised.^{9,15} To address some of these concerns, the use of live-streaming video conferencing technology was introduced to allow

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patients to be observed remotely in the privacy of their own homes or other preferred locations, eliminating the need for DOT workers to enter personal space or for patients to travel to the clinic. A study in Canada reported that patients on anti-tuberculosis treatment were highly satisfied with the flexibility, privacy, and efficiency of monitoring using video DOT (VDOT).¹⁶ VDOT has also been found to be a cost-effective alternative to in-person DOT.^{17–19} One study reported an average cost savings of US\$2448 per patient over the course of treatment.¹⁷ Another study showed that recorded VDOT, allowing patients to send video recordings of themselves ingesting these medications, was preferred by patients to in-person DOT.²⁰

In 2013, NYC DOHMH implemented the use of live VDOT for eligible patients on anti-tuberculosis treatment. The objectives of the project were to determine if treatment completion with VDOT was comparable to that of in-person DOT, to ascertain whether the use of VDOT for NYC TB patients was feasible and acceptable, and to describe the resource and staffing needs for monitoring treatment with VDOT.

STUDY POPULATION AND METHODS

Patients were enrolled prospectively from September 2013 to September 2014, and were followed for 9 months or until discharge, e.g., completed treatment, lost to care, or refused to continue treatment. Patients on VDOT had to be eligible for DOT, aged ≥ 18 years, and speak English or Spanish, as these were the languages spoken by the assigned VDOT worker. Patients were required to have private space to conduct VDOT, to be proficient at using a smartphone with video conferencing capability after receiving training, and to be able to identify and self-administer the prescribed medications. Patients were not eligible if they had a history of adverse reaction(s) to the prescribed medications, were at increased risk for hepatic complications, or had a history of non-adherence. Prior to beginning VDOT, patients were observed for 2 weeks in the clinic, as is standard for all patients enrolling in DOT.

Patients meeting the inclusion criteria were offered VDOT and signed an agreement form. Once enrolled, patients were loaned a DOHMH smartphone pre-programmed with video conferencing software. Patients were trained by DOHMH staff to use the smartphones and follow the VDOT process. At enrollment, the VDOT worker asked the patients three open-ended questions about their reasons for accepting VDOT.

VDOT process

Two staff members were trained and assigned to conduct all VDOT sessions: one VDOT worker with

previous experience conducting in-person DOT and one back-up staff member. The VDOT worker and patient pre-arranged a schedule for the VDOT calls. The VDOT worker received calls using a webcam-equipped computer. Patients were asked about side effects, and if none were reported, the patient showed and named each pill in front of the camera before swallowing it. To demonstrate that the pills had been swallowed, the patients opened their mouths in front of the camera and engaged in conversation with the VDOT worker for several minutes. If any side effects were reported, a DOHMH physician was connected by video or audio to provide medical advice. Each VDOT session was documented in the DOHMH electronic medical record (EMR) system. Technical or operational issues were directed to supervisors for resolution and tracked in a separate database. Missed VDOT appointments were followed up by phone calls and, if these were unsuccessful, home visits. The VDOT worker recorded the start and end time of each session, including the time it took to document the session, in the EMR and the VDOT database.

Analysis

The characteristics and treatment outcomes of patients enrolled in the VDOT project from September 2013 to September 2014 were compared to those of patients aged ≥ 18 years receiving standard in-person DOT during the same period. Patients on in-person DOT were defined as those who had at least one dose of medication observed at a health department or hospital clinic or in the community and underwent no VDOT observation. For both VDOT and in-person DOT, analysis for treatment completion was limited to patients eligible to complete treatment. Patients were excluded if they were determined not to have TB, died during treatment, moved outside of the United States prior to completing treatment, or were still on treatment at the end of the study.

The proportion of successful VDOT sessions was calculated and compared to the proportion of successful in-person DOT sessions conducted by DOHMH DOT workers during the study period. A session was considered successful if a patient was observed ingesting the full dose of prescribed medication on the scheduled day and time. The median time in minutes of VDOT sessions was calculated. Technical issues encountered during VDOT sessions and patients' reasons for accepting VDOT were reviewed and grouped. The number of VDOT observations that a DOT worker was able to conduct each day was compared to those conducted with in-person DOT.

Data were obtained from the NYC TB registry, the TB clinic EMR, and the VDOT database. Pearson's χ^2 or Fisher's exact test was used to test for statistical significance for categorical variables and the Wilcoxon

Table 1 Characteristics of patients treated for tuberculosis under in-person DOT and VDOT, New York City, September 2013–September 2014

| | In-person DOT <i>n</i> (%) | VDOT <i>n</i> (%) | <i>P</i> value |
|--|-------------------------------|----------------------|----------------|
| Total | 329 | 61 | |
| Male sex | 199 (60) | 38 (62) | 0.79 |
| Age, years, median (range) | 48 (18–101) | 36 (18–85) | <0.01 |
| US-born* | 35 (11) | 5 (8) | 0.56 |
| Human immunodeficiency virus | | | |
| Positive | 15 (5) | 6 (10) | 0.22 |
| Negative | 270 (82) | 51 (84) | |
| Unknown | 44 (13) | 4 (7) | |
| Pulmonary disease | 275 (84) | 47 (77) | 0.22 |
| Cavitary chest radiograph [†] | 43 (16) | 10 (21) | 0.18 |
| Ever respiratory smear-positive [†] | 145 (53) | 30 (64) | 0.16 |
| Culture-positive | 249 (76) | 51 (84) | 0.18 |
| Drug resistance [‡] | 20 (8) | 22 (43) | <0.01 |
| Treated at DOHMH TB clinic [§] | 187 (57) | 55 (90) | <0.01 |

* Includes patients born in the United States, Puerto Rico, and other US territories.

[†] Among patients with pulmonary TB disease.

[‡] Among patients with a positive culture for *Mycobacterium tuberculosis*.

[§] Last treatment provider was the New York City DOHMH TB clinic.

DOT = directly observed therapy; VDOT = video DOT; DOHMH = Department of Health and Mental Hygiene; TB = tuberculosis.

on rank-sum test for continuous data. A 5% significance level was used for both tests.

Ethics

The DOHMH's legal team and information technology (IT) office ensured that the implementation of VDOT met the Health Insurance Portability and Accountability Act (HIPAA) patient privacy requirements, and that the video conferencing software met IT security standards. The study did not require patient informed consent, as the data were collected as part of routine TB case management practice. The NYC DOHMH Institutional Review Board determined the study to be a public health program evaluation that was not research, and ethical approval was not required. Twenty-five smartphones with data plans and three licenses for use of the video conferencing software were donated for the study.

RESULTS

From September 2013 to September 2014, 390 patients were enrolled on DOT, 61 (16%) on VDOT and 329 (84%) on in-person DOT. Compared to patients receiving in-person DOT, VDOT patients were younger, more likely to have resistance to at least one anti-tuberculosis medication, and more likely to be treated at one of the DOHMH TB clinics (Table 1). Among those eligible to complete treatment, 47 (96%) of 49 patients on VDOT completed treatment compared to 260/267 (97%) patients on in-person DOT ($P = 0.63$) (Table 2). Fifty-nine patients (53 on in-person DOT and 6 on VDOT) were still on treatment after 9 months of follow-up due to intolerance of or resistance to rifampin, extensive

Table 2 Treatment outcomes of patients treated for tuberculosis under DOT and VDOT, New York City, September 2013–September 2014

| | In-person DOT <i>n</i> (%) | VDOT <i>n</i> (%) | <i>P</i> value |
|--|-------------------------------|----------------------|----------------|
| Total patients eligible to complete treatment | 267 | 49 | |
| Completed | 260 (97) | 47 (96) | 0.80 |
| Lost | 2 (1) | 1 (2) | |
| Refused | 4 (1) | 1 (2) | |
| Adverse reaction | 1 (1) | 0 | |
| Total patients not eligible to complete treatment* | 62 | 12 | |
| Moved out of the United States | 6 (10) | 1 (8) | <0.01 |
| Died | 3 (5) | 1 (8) | |
| Currently on treatment | 53 (85) | 6 (50) | |
| Not a TB case | 0 | 4 (33) | |

* Reasons patients were not eligible to complete treatment at the time of the study include leaving the United States prior to treatment completion, died prior to completing treatment, treatment extended due to intolerance or resistance to rifampin, extensive TB disease or treatment interruption, and treatment stopped after TB diagnosis was ruled out. DOT = directly observed therapy; VDOT = video DOT; TB = tuberculosis.

TB disease, or interruption of treatment due to side effects. Of 61 patients who responded to the open-ended questions, 59 (97%) reported choosing VDOT due to its convenience ($n = 58$), followed by privacy ($n = 4$) and flexibility ($n = 1$).

Of the 3455 sessions scheduled for patients on VDOT, 3292 (95%) were successfully conducted, compared to 32 204/35 442 (91%) among patients on in-person DOT ($P < 0.01$). The median period on VDOT was 161 days (interquartile range [IQR] 39–239). The median time for a VDOT session was 5 min (IQR 5–6). Four sessions extended beyond 20 min due to medical consultations for side effects. After consultation, three patients were able to continue treatment on VDOT. TB was ruled out for the remaining patient, and treatment was discontinued. VDOT enabled a DOT worker to observe a maximum of 25 patients/day compared with 25 patients/day for DOT workers who conducted observations in the clinic, and 12 patients/day for DOT workers who conducted observations in the community.

Of 346 VDOT-related issues identified for 54 patients, 276 were technical problems; 49 were patient-related challenges such as patients forgetting their appointment, having schedule conflicts, or patient being out of camera view; and 21 were due to smartphone misuse (Table 3). Staff worked with the DOHMH Information Technology department, the video conferencing software support group, and patients to resolve many of the technical problems specific to video and audio connections (Table 4).

DISCUSSION

For over 20 years, DOT has been an integral part of the NYC DOHMH's TB control efforts, and has improved patient outcomes by increasing treatment

Table 3 Issues encountered during VDOT sessions, New York City ($n = 346$)

| Type of issue | Number of times encountered |
|---|-----------------------------|
| Technical | 276 |
| Slow internet connection | 72 |
| Smartphone malfunction, e.g., battery not charged, video and audio not working | 191 |
| Computer and software malfunctions | 13 |
| Patient-related | 49 |
| Patient forgot medication at home, forgot appointment, or unable to find a private location | 26 |
| Patient had conflict with work or school schedule | 4 |
| Patient was out of camera view | 19 |
| Smartphone misuse | 21 |
| Patient could not operate smartphone, broke accessories, and blocked camera | 18 |
| Exceeded allotted data plan usage | 3 |
| Total | 346 |

VDOT = video directly observed therapy.

completion rates.¹³ However, DOT is costly and requires large numbers of staff. This study demonstrates that VDOT can be a successful method for delivering DOT services, with over 3000 VDOT sessions conducted. Treatment completion with VDOT was high, similar to that of in-person DOT, and VDOT workers observed over twice as many patients/day as DOT workers observing patients in the community.

An important component of DOT is establishing a relationship of trust between the patient and the DOT worker. Some may argue that the lack of human

interaction, which is part of traditional DOT, might lead to less successful outcomes with VDOT. Gassanov et al. reported that although interpersonal interactions between patients and DOT workers diminished with VDOT, the treatment outcomes of patients on VDOT and in-person DOT were similar.¹⁶ While our study also found very high treatment completion rates regardless of DOT method—96% with VDOT vs. 97% with in-person DOT—VDOT workers reported that they were able to establish and maintain good relationships with their patients in the same manner as with in-person DOT. No significant complaints were made about VDOT by patients during the enrollment and follow-up periods. Further study is needed to better understand patient experiences with VDOT.

Several advantages to VDOT were identified. Patients who chose VDOT over in-person DOT reported that it was more convenient than traveling to the clinic or arranging in-person visits. Furthermore, unlike in-person DOT, VDOT is not interrupted by inclement weather or patients traveling outside the city. Several patients in our study who vacationed or worked outside of NYC during their treatment underwent DOT successfully by video. During a snowstorm, both patients and staff benefited from VDOT by not having to travel for observations.

Challenges with VDOT were also encountered: connectivity problems, misuse of phones and phone accessories, and patients forgetting or having scheduling conflicts impeded some observations. However, as reported in other studies, some of these challenges were overcome by working with patients to identify

Table 4 Technical issues and solutions related to VDOT, New York City

| Type of issues | Description | Solutions |
|---|---|---|
| Absence of or interruptions in audio | Microphone on patient's smartphone was turned off | Asked patient to check the smartphone microphone setting |
| | Patient's smartphone connection was weak | Checked internet traffic patterns |
| | Updates in the video software | Discontinued conference call and reconnected |
| | Changes in DOHMH servers | Contacted software company about software updates |
| Poor video quality including no video, poor lighting, or video freezing | Contacted DOHMH IT administrator about server changes | |
| | Smartphone connection was weak | Asked patient to check smartphone signal strength |
| | Patient was in a dimly lit area | Asked patient to move to an area with more lighting or better signal |
| | Incorrect camera setting on patient's smartphone | Asked patient to make sure camera was on and forward facing as if taking a 'selfie' |
| | High volume of internet traffic | Checked with DOHMH IT administrator to make sure video streaming was not being blocked |
| Unable to connect to the video conferencing software | More than one VDOT worker using the same account to access the same video conference line | Requested DOHMH IT administrator to open more ports for video transmission |
| | Patient had the wrong conference number | Retrained VDOT workers to use their individual accounts to generate conference sessions |
| | Patient's smartphone had weak reception | Called patient and confirmed conference number |
| | Smartphone malfunction | Asked patient to check their internet connection |
| | Problems with conference server | VDOT observer restarted computer or video conference software |
| | | Contacted DOHMH IT administrator |
| | | Contacted video conference software provider customer support |
| | Updated video conference software or replaced smartphone as needed | |

VDOT = video directly observed therapy; DOHMH = Department of Health and Mental Hygiene; IT = information technology.

and solve the problems.^{16,18,19} As technology improves and the population becomes more comfortable with video technology, there will be fewer technical challenges. Further understanding of these obstacles and the VDOT worker-patient relationship is needed.

Use of video technology for monitoring patients on treatment for TB has been shown to be cost-effective and require less staff time.^{18,19} While our study did not include a cost calculation, it found that VDOT maximized staff resources, allowing staff to observe twice the number of patients seen under community-based DOT. This could enable the DOHMH to sustain DOT services while reassigning staff to other essential TB control efforts. The ability to have real-time video consultations with physicians also reduces the need for clinic visits, and VDOT furthermore reduces the costs of car maintenance and transportation. However, the need to purchase smartphones (for patients who do not have access to a private or video-compatible smartphone), data plans, and HIPAA-compliant video conferencing software are expenses that need to be taken into account. The DOHMH has recently begun allowing patients to use video conferencing software on their personal devices for VDOT, and prioritizes lending smartphones to those without access to a video-enabled device. This reduces costs for the DOHMH and is likely preferred by patients, as it eliminates the need to learn to use a new device. Published cost-analysis studies on VDOT have been limited to fewer than 100 patients.^{18,19} As VDOT is expanded, large-scale cost-effectiveness analysis is needed to determine the economic impact of VDOT.

The concept of remote monitoring of patients was new to staff. Staff training and support ensured that VDOT workers were comfortable with the process, the need for patient confidentiality and privacy, and the video conferencing software and equipment, effecting successful integration of VDOT into the existing DOT program. However, because the VDOT project was program-based and was not designed as a research study, certain data were not collected or available for analysis. First, as enrollment of patients to VDOT was limited by the availability of phones, the overall proportion of patients eligible for and accepting and refusing VDOT could not be assessed. Second, the number of days during which patients remained on in-person DOT was not available for comparison with VDOT. However, analysis of overall adherence was reported and compared to in-person DOT. Finally, the VDOT eligibility criteria could have favored patients who were more likely to complete treatment. However, this study shows that VDOT is an effective option for those eligible patients who elect to use it.

In conclusion, the study found that treatment completion with VDOT was high. VDOT maximized

staff utilization, and offered a more flexible and convenient alternative to in-person DOT for many patients. Further study is needed to analyze the economic benefits of VDOT.

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RESUME

CONTEXTE : Le traitement sous observation directe (DOT), le standard en matière de suivi des patients sous traitement de la tuberculose (TB), requiert des ressources substantielles en matière de personnel de santé, et il peut être malcommode et perturbant pour les patients.

OBJECTIF : Déterminer si une technique de vidéo permettant d'observer les patients sous traitement TB à distance (VDOT) est aussi efficace que le DOT fait en personne.

SCHEMA : Les patients TB éligibles à New York ont été prospectivement enrôlés dans un VDOT de septembre 2013 à septembre 2014. Nous avons comparé les résultats du traitement et le rendement des prestataires pour le VDOT et le DOT en personne.

RÉSULTATS : Sur 390 patients sous DOT pour un traitement de TB, 61 (16%) ont été sous VDOT et 329

(84%) sous DOT en personne. L'adhésion aux sessions de VDOT prévues a été de 95% (3292/3455) comparée à 91% (32 204/35 442) pour le DOT en personne ($P < 0,01$). Le VDOT a permis à un travailleur d'observer un maximum de 25 patients par jour, ce qui a été similaire aux prestataires de DOT qui ont observé les patients dans une structure de santé ($n = 25$), mais deux fois plus élevé que les prestataires de DOT qui ont observé les patients dans la communauté ($n = 12$). L'achèvement du traitement avec le VDOT a été similaire à celui du DOT en personne (96% contre 97% ; $P = 0,63$). Les problèmes majeurs rencontrés lors des sessions VDOT ont été les interruptions de la connexion vidéo et audio. **CONCLUSION :** La mise en œuvre du VDOT a abouti à un bon résultat du traitement de TB, tout en maximisant les ressources du Ministère de la santé.

RESUMEN

MARCO DE REFERENCIA: El tratamiento directamente observado (DOT), que constituye la norma de atención en el seguimiento de los pacientes que reciben tratamiento por tuberculosis (TB), exige considerable recursos de los ministerios de salud y puede ser inapropiada y problemática para los pacientes.

OBJETIVO: Determinar si la tecnología de videosupervisión a distancia de los pacientes que reciben tratamiento antituberculoso (VDOT) es tan eficaz como la supervisión en persona de DOT.

MÉTODOS: Se incorporaron al estudio VDOT de manera prospectiva pacientes idóneos con diagnóstico de TB entre septiembre del 2013 y septiembre del 2014 en la ciudad de Nueva York. Se compararon los desenlaces terapéuticos y el rendimiento de los trabajadores de salud con VDOT y DOT.

RESULTADOS: De los 390 pacientes en tratamiento antituberculoso, 61 siguieron la supervisión a distancia

VDOT (16%) y 329 la supervisión personal DOT (84%). El cumplimiento terapéutico de las sesiones VDOT programadas fue 95% (3292/3455), en comparación con 91% en la supervisión DOT (32 204/35 442) ($P < 0,01$). El VDOT permitió al trabajador de salud observar un máximo de 25 pacientes por día, lo cual equivale al número de pacientes observados en el consultorio ($n = 25$), pero es el doble del número de pacientes observados en la comunidad ($n = 12$). La compleción del tratamiento con el seguimiento VDOT fue análoga a la compleción con el seguimiento DOT personal (96% contra 97%; $P = 0,63$). Los principales problemas encontrados en las sesiones VDOT fueron la interrupción de la conectividad visual y auditiva.

CONCLUSIÓN: La aplicación de VDOT dio lugar a desenlaces favorables del tratamiento antituberculoso y al mismo tiempo potenció al máximo los recursos del Ministerio de Salud.