MEETING SUMMARY
ASCO 2020, VIRTUAL MEETING

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HIGHLIGHTS FROM GI NURSES CONNECT
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USING DIGITAL ENGAGEMENT TO PROACTIVELY MANAGE SYMPTOMS IN PATIENTS ON CAPECITABINE

Sohal M, et al.
ASCO 2020. Abstract #4605. Poster presentation
BACKGROUND AND METHODS

Background

• Capecitabine may cause patients to experience AEs, in particular HFS and diarrhoea, which may lead to non-adherence\(^1,2\)

• Digital patient engagement has been used in cancer care to monitor AEs and improve patient adherence\(^3\)

Methods

• Patients received messages and respondents who reported AEs were engaged by nurses via a secure platform\(^1\)

• Nurses made pharmacologic or non-pharmacologic recommendations or referred to an oncologist\(^1\)

AE, adverse event; HFS, hand–foot syndrome
DEMOGRAPHICS AND OUTCOMES

- Patients treated with capecitabine were sent 1,421 messages, receiving 658 (46.3%) replies
  - 105 (16%) of messages from 95 patients indicated experience of diarrhoea or HFS
- Referral to an oncologist was more common for HFS (66.7%) than for diarrhoea (33.3%)
- Adherence (PDC) was significantly better in the intervention group (Figure 1)
- Resolution of symptoms was more common in patients recommended self care than in those referred to an oncologist, loss to follow-up was more common in the self care group (Figure 2)

Figure 1: PDC 30-day post-intervention

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=44)</th>
<th>Control (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDC (%)</td>
<td>68.8</td>
<td>79.3</td>
</tr>
</tbody>
</table>

*Statistically significant at P=0.038

Figure 2: Outcomes by intervention type

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Self care</th>
<th>Referral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms resolved (n=17)</td>
<td>33.3</td>
<td>22.2</td>
</tr>
<tr>
<td>Medication change (n=4)</td>
<td>4.4</td>
<td></td>
</tr>
<tr>
<td>Symptom treatment prescribed (n=2)</td>
<td>2.2</td>
<td>11.1</td>
</tr>
<tr>
<td>Loss to follow-up (n=31)</td>
<td>60</td>
<td>44.4</td>
</tr>
</tbody>
</table>

HFS, hand–foot syndrome; PDC, proportion of days covered
CONCLUSIONS

- The SMS and nurse-led secure messaging system facilitated clinical interventions by nurse care managers
- Adherence was improved in the intervention group
- The authors suggested that nurse-led digital engagement is effective in increasing engagement of cancer patients treated with oral therapy who are suffering from AEs
HOME-BASED MANAGEMENT OF CANCER PATIENTS (CPS) EXPERIENCING TOXICITIES WHILE ON ANTICANCER TREATMENT: THE IMPACT OF A NURSE-LED TELEPHONE TRIAGE (NTT)

BACKGROUND AND METHODS

Background

• **The cost of cancer care is increasing rapidly**, and health care provision are not keeping pace\(^1\)
  – Increased cost of therapies has a role to play\(^1\)
  – **Focusing on treatment-related AEs and hospitalizations can reduce costs**\(^2\)

• Use of CTCAE in clinical practice may facilitate early intervention and reduce resource utilisation and costs\(^3\)

Methods

• Assess a NTT to reduce hospitalisation\(^3\)
  – Assessment of AEs according to CTCAE v4.1 by trained oncology nurses
  – Intervention over the phone for Grade 1-2, immediate referral for ≥3

AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; NTT, Nurse-led Telephone Triage
DEMOGRAPHICS, PRIMARY, AND SECONDARY OUTCOMES

- Breast, colorectal and lung were the main cancer types (Figure 1)
- Primary endpoint: hospitalisations were reduced from 2017-2018 to 2018-2019 (Figure 2)
- Secondary endpoints:
  - 117 (27.3%) patients reported > 1 AE during NTT consultation
    - AEs G1 237 (40.8%), G2 231 (39.8%), G3–G4 113 (19.4%)
  - Lung cancer patients most frequent callers (22.4%)
  - Lung, pancreatic and gastric patients had the highest rate of AEs
  - Estimated annual cost saving for single Italian centre €380,160

Figure 1: CPs on treatment

Figure 2: Hospitalisations

AE, adverse event; CP, cancer patients; G, grade; NTT, Nurse-led Telephone Triage; ENT, ear, nose and throat.
CONCLUSIONS

- NTT successfully reduced the rate of hospitalisation for CP receiving treatment
- A focus on lung cancer patients may be particularly effective due to their substantial use of the NTT and complex symptoms
- Substantial cost savings were achieved (€380,160)
- NTT implementation into a regional network is planned
INTERVENTION COMBINING NURSE NAVIGATORS (NNS) AND A MOBILE APPLICATION VERSUS STANDARD OF CARE (SOC) IN CANCER PATIENTS (PTS) TREATED WITH ORAL ANTICANCER AGENTS (OAA): RESULTS OF CAPRI, A SINGLE-CENTER, RANDOMIZED PHASE III TRIAL

Mir O, et al.
Background

- Remote monitoring systems may improve follow-up and patient care\textsuperscript{1,2} – There is a need for prospective data on these systems

Methods

- Single-centre randomised phase 3 trial conducted in a tertiary-care setting

**Excluded:** treatment in a clinical trial or compassionate use program, hormonal therapy alone

**Web/mobile application:**
- Dashboard for NNs to manage patients’ records
- Interface for other healthcare professionals
- Patients can record tracking data, contact nurses via secure messaging, view therapy and side effect information or store documents

**Standard of care**
- Nurse navigator (NN)
  - Weekly calls for 1 month then every other week
  - Hotline Mon-Fri 09 AM – 05 PM
- Dedicated website / mobile application
  - 80 algorithms ≥ specific alerts

**For 6 months**

Adult cancer patients
- Advanced disease
- Approved oral treatment
- Solid tumours
- PS <3

R 1:1

NN, nurse navigator; PS, performance status; R, randomisation
DEMOGRAPHICS, PRIMARY, AND SECONDARY OUTCOMES

• The majority of the enrolled patients (N=559) were women (59.0%), with a substantial elderly population (>75 years: 14.0%), and use of targeted therapy (60.6%)
  – All primary tumour sites were represented

• Primary endpoint RDI
  – Improvement in mean (SD) adherence-adjusted RDI (0.8417 [0.2632] vs 0.7998 [0.2090] for the intervention vs SoC groups, respectively; P=0.0451)

• Secondary endpoints
• Patients experiencing Grade ≥ 3 toxicities were reduced with the intervention vs SoC, respectively (Figure)
  – Patient experience improved: mean (SD) PACIC global score: 2.94 (0.83) vs 2.67 (0.89); P=0.01
  – Use of supportive care increased in the intervention group: 43.8% vs 35.2%, P=0.04

RESULTS

PACIC, Patients Assessment Chronic Illness Care; RDI, relative dose-intensity; SD, standard deviation; SoC, standard of care
RESULTS AND CONCLUSIONS

RESULTS

• Secondary endpoints (cont.)
  – The proportion of patients hospitalised improved (Figure)
  – Mean (SD) days of hospitalisation improved with the intervention vs SoC, respectively: 2.82 (6.96) vs 4.44 (9.60); P=0.02

CONCLUSIONS

• The NN intervention improved:
  – RDI
  – Patient experience
  – Number and duration of hospitalisations
  – Treatment related Grade ≥3 toxicities

• Future studies focussed on adherence, specific tumours, and drug classes should be carried out

NN, nurse navigator; RDI, relative dose-intensity; SoC, standard of care
DONAFENIB VERSUS SORAFENIB AS FIRST-LINE THERAPY IN ADVANCED HEPATOCELLULAR CARCINOMA: AN OPEN-LABEL, RANDOMIZED, MULTICENTER PHASE II/III TRIAL

Bi F et al.
ASCO 2020. Abstract #4605. Oral presentation


Background

- **HCC has a insidious and rapid onset, often resulting in late diagnosis**\(^1\)
  - >50% of global cases and deaths occur in China\(^2\)
  - Sorafenib is the standard first-line therapy, median OS is lower in China (6.5–11.4 months) than globally (10.7–14.7 months)\(^3\-\^{12}\)

Methods

- Multi-centre phase 2/3 trial conducted at 37 Chinese sites\(^1\)

**Study design**

- **Key inclusion criteria:**
  - 18–75 years
  - ≥1 measurable lesion
  - Unresectable or metastatic HCC
  - Child-Pugh score ≤7
  - No prior systemic treatment
  - ECOG 0-1

- **Stratified by:**
  - AFP level: <400 µg/L vs ≥400 µg/L
  - Previous locoregional therapy: Yes vs no
  - BCLC staging: B vs C
  - Portal vein invasion and/or extrahepatic metastasis: present vs absent

- **Patients with unresectable or metastatic HCC** (N=668) → **Donafenib (0.2 g bid)** → **R** 1:1 → **Sorafenib (0.4 g bid)** → **Until intolerable toxicity or disease progression (according to RECIST 1.1)** → **Primary endpoint:** OS
  - Secondary endpoints: PFS, ORR, DCR, AEs

References:

DEMOGRAPHICS, PRIMARY, AND SECONDARY OUTCOMES

• Patient characteristics were well balanced between groups (N=659)
  — BCLC stage C (87.4%), PVI and/or EHS (73.4%), and HBV aetiology (90.1%)

• Primary endpoint: demonstrated superiority of donafenib vs sorafenib for OS in the FAS population (Figure)\(^a\)

• Secondary endpoints
  — Efficacy outcomes for donafenib and sorafenib were similar
    • PFS (HR [95% CI]: 0.909 [0.763, 1.082]; P=0.2824), respectively
    • ORR (4.6% vs 2.7%; P=0.2488), respectively
    • DCR (30.8% vs 28.7%; P=0.5532), respectively

\(^a\)ITT results were similar

BCLC, Barcelona Clinic Liver Cancer; CI, confidence interval; DCR, disease control rate; EHS, extrahepatic spread; FAS, full analysis set; HBV, hepatitis B virus; HR, hazard ratio; mOS, median overall survival; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PVI, portal vein invasion

RESULTS AND CONCLUSION

RESULTS

- AEs were less common with donafenib than sorafenib (Figure)
  - Grade ≥3 (57.4% vs 67.5%; P=0.0082);
  - AEs leading to treatment interruption (30.3% vs 42.5%; P=0.0013)

CONCLUSIONS

- Donafenib demonstrated superiority over sorafenib for OS in Chinese patients with HCC
- Safety and tolerability were improved with donafenib
- The authors suggested that donafenib should be considered as the first-line therapy for advanced HCC

AE, adverse event; HCC, hepatocellular carcinoma; OS, overall survival
SUMMARY
Closing thoughts from Brittni Prosdocimo

- A well thought out and implemented approach to nurse-lead triage for side-effect reduction is an important area to focus future research.
- Everyday technology like mobile applications can allow tracking of oral chemotherapy to improve patients outcomes.
- These data from ASCO back up practices being implemented empirically where by nurses proactively follow-up of patients using oral oncolytics in order to monitor their care and reduce adverse events.
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