Date:
31.03.2022

Certificate of Approval from CDSIMER-IEC

To

Mr. Vishal K R

2nd Year MBBS Student,

CDSIMER

Study Ref: CDSIMER/MR/0008/IEC/2022

Dear Mr. Vishal K R,

CDSIMER-IEC reviewed and discussed your application received from Internal Scientific Committee to conduct the research study entitled "A Study of Paracetamol Poisoning Induced Acute Liver Injury at a Tertiary Care Centre" during the CDSIMER IEC meeting held on dated 08-03-2022 between 2.00 pm to 3.45 pm at Board room, G Block, Dr. Chandramma Dayanand Sagar Institute of Medical Education and Research (CDSIMER).

The following documents were reviewed:

1. Study Protocol
2. Data Collection Proforma

The following members of the CDSIMER-IEC were present at the meeting

Sl. No	Name	Designation
1	Shri. M N Vidyashankar	Chairperson
2	Dr. Pratibha D Nadig	Member secretary
3	Dr. Meena Nandimath	Basic Medical Scientist
4	Shri. Arvind Moorchung	Legal Expert
5	Dr. S Rajagopalan	Clinician
6	Dr. Manju Prakash	Clinician
7	Dr. Yashaswini L S	Clinician
8	Dr. Amita Mukhopadhyay	Clinician
9	Dr. Aravind G N	Clinician
10	Smt. Durga Unnikrishnan	Social Scientist/Ethicist
11	Mr. Sheik Alaudeen M S	Lay Person

The study is **APPROVED** in its revised form.

Received K.R.Vishal
19/05/2022

Date:

Following points must be noted (whichever is applicable):

1. CDSIMER IEC should be informed of the date commencement of study and submit quarterly progress reports.
2. PI and other investigator should co-operate with CDSIMER IEC, which may monitor study from time to time.
3. New information or any SAE, which could affect this study, must be communicated to CDSIMER IEC and sponsors (If applicable). The PI should report SAEs occurred for CDSIMER IEC approved studies within 24 hrs of the occurrence of the SAE.
4. In the event of any protocol amendments, CDSIMER IEC must be informed and the amendments should be highlighted in clear terms as follows:

a) The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project (Page No., Clause No. etc.)
b) The PI must comment how proposed amendment will affect the ongoing study
c) Alteration in the budgetary status, staff requirement should be clearly indicated and the revised budget form should be submitted.
d) If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval,
e) If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
f) If there are any amendments in the trial design, these must be incorporated in the protocol and other study document. These revised documents should be submitted for approval of the CDSIMER IEC, only then can they be implemented.
g) Approval for amendment changes must be obtained prior to implementation of changes.
h) The amendment is unlikely to be approved by the CDSIMER IEC unless all the above information is provided.

5. Any deviation/violation/waiver in the protocol must be informed to the CDSIMER IEC.

If project initiation not done in next 1 year from the date of approval from CDSIMER IEC, further extension will not be granted and it will require resubmission to CDSIMER IEC.

Thanks and Regards,

Dr.Pratibha Nadig

Member Secretary

Member Secretary
CDSIMER - IEC
Dr. Chandramma Dayananda Sagar Institute
of Medical Education & Research
Devarakaggalahalli, Harohalli,
Kanakapura Taluk, Ramanagara District - 562112

Date:

31.03.2022

Certificate of Approval from CDSIMER-IEC

To

Ms. Yuktha Hadly Devaraju,

2nd Year MBBS Student,

CDSIMER

Study Ref: CDSIMER/MR/0009/IEC/2022

Dear Ms.Yuktha Hadly Devaraju,

CDSIMER-IEC reviewed and discussed your application received from Internal Scientific Committee to conduct the research study entitled "SARS CoV-2 IgG Antibody Response to Booster dose" during the CDSIMER IEC meeting held on dated 08-03-2022 between 2.00 pm to 3.45 pm at Board room, G Block, Dr. Chandramma Dayanand Sagar Institute of Medical Education and Research (CDSIMER).

The following documents were reviewed:

1. Study Protocol
2. Informed Consent Form with translation in Kannada language

The following members of the CDSIMER-IEC were present at the meeting

Sl. No	Name	Designation
1.	Shri. M N Vidyashankar	Chairperson
2	Dr. Pratibha D Nadig	Member secretary
3	Dr. Meena Nandimath	Basic Medical Scientist
4	Shri. Arvind Moorchung	Legal Expert
5	Dr. S Rajagopalan	Clinician
6	Dr. Manju Prakash	Clinician
7	Dr. Yashaswini L S	Clinician
8	Dr. Amita Mukhopadhyay	Clinician
9	Dr. Aravind G N	Clinician
10	Smt. Durga Unnikrishnan	Social Scientist/Ethicist
11	Mr. Sheik Alaudeen M S	Lay Person

The study is **APPROVED** in its revised form.

Date:

Following points must be noted (whichever is applicable):

1. CDSIMER IEC should be informed of the date commencement of study and submit quarterly progress reports.
2. PI and other investigator should co-operate with CDSIMER IEC, which may monitor study from time to time.
3. New information or any SAE, which could affect this study, must be communicated to CDSIMER IEC and sponsors (If applicable). The PI should report SAEs occurred for CDSIMER IEC approved studies within 24 hrs of the occurrence of the SAE.
4. In the event of any protocol amendments, CDSIMER IEC must be informed and the amendments should be highlighted in clear terms as follows:

a) The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project (Page No., Clause No. etc.)
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f) If there are any amendments in the trial design, these must be incorporated in the protocol and other study document. These revised documents should be submitted for approval of the CDSIMER IEC, only then can they be implemented.
g) Approval for amendment changes must be obtained prior to implementation of changes.
h) The amendment is unlikely to be approved by the CDSIMER IEC unless all the above information is provided.

5. Any deviation/violation/waiver in the protocol must be informed to the CDSIMER IEC.

If project initiation not done in next 1 year from the date of approval from CDSIMER IEC, further extension will not be granted and it will require resubmission to CDSIMER IEC.

Thanks and Regards,

Dr.Pratibha Nadig

Member Secretary

Member Secretary
CDSIMER - IEC
Dr. Chandramma Dayananda Sagar Institute
of Medical Education & Research
Devarakaggalahalli, Harohalli,
Kanakapura Taluk, Ramanagara District - 562112

Date:

25.04.2022

Certificate of Approval from CDSIMER-IEC

To

Ms.Ananya S,

Principal Investigator,

2nd Year MBBS Student, CDSIMER

Study Ref: CDSIMER/MR/0012/IEC/2022

Dear Ms. Ananya S,

CDSIMER-IEC reviewed and discussed your application received from Internal Scientific Committee to conduct the research study entitled "A Cross sectional observational study to evaluate the adverse events of Dapaglifozin among type II diabetes mellitus patients in a tertiary care hospital" during the CDSIMER IEC meeting held on dated 12-04-2022 between 2.00 pm to 4.00 pm at Board room, G Block, Dr. Chandramma Dayanand Sagar Institute of Medical Education and Research (CDSIMER).

The following documents were reviewed:

1. Study Protocol
2. Informed Consent Form with Kannada Language
3. Case Report Form
4. Questionnaire with Kannada Language

The following members of the CDSIMER-IEC were present at the meeting

Sl. No	Name	Designation
1	Shri. M N Vidyashankar	Chairperson
2	Dr. Pratibha D Nadig	Member secretary
3	Dr. Meena Nandimath	Basic Medical Scientist
4	Shri. Arvind Moorchung	Legal Expert
5	Dr. S Rajagopalan	Clinician
6	Dr. Yashaswini L S	Clinician
7	Dr. Amita Mukhopadhyay	Clinician
8	Dr. Aravind G N	Clinician
9	Smt. Durga Unnikrishnan	Social Scientist/Ethicist
10	Mr. Sheik Alaudeen M S	Lay Person

The study is **APPROVED** in its presented form.

Reviewed

25/04/22

Following points must be noted (whichever is applicable): Date:

1. CDSIMER IEC should be informed of the date commencement of study and submit quarterly progress reports.
2. PI and other investigator should co-operate with CDSIMER IEC, which may monitor study from time to time.
3. New information or any SAE, which could affect this study, must be communicated to CDSIMER IEC and sponsors (If applicable). The PI should report SAEs occurred for CDSIMER IEC approved studies within 24 hrs of the occurrence of the SAE.
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g) Approval for amendment changes must be obtained prior to implementation of changes.
h) The amendment is unlikely to be approved by the CDSIMER IEC unless all the above information is provided.

5. Any deviation/violation/waiver in the protocol must be informed to the CDSIMER IEC.

If project initiation not done in next 1 year from the date of approval from CDSIMER IEC, further extension will not be granted and it will require resubmission to CDSIMER IEC.

Thanks and Regards,

Dr.Pratibha Nadig

Member Secretary

Member Secretary
CDSIMER - IEC
Dr. Chandramma Dayananda Sagar Institute
of Medical Education & Research
Devarakaggalahalli
Kanakapura Taluk,

Received
Anusha S S
18/8/2022

Date:
25.04.2022

Certificate of Approval from CDSIMER-IEC

To

Ms. Uppada Vibha,

Principal Investigator,

2nd Year MBBS Student, CDSIMER

Study Ref: CDSIMER/MR/0013/IEC/2022

Dear Ms. Uppada Vibha,

CDSIMER-IEC reviewed and discussed your application received from Internal Scientific Committee to conduct the research study entitled "A cross-sectional observational study on Adverse drug reactions of antitubercular drugs at tertiary care centre" during the CDSIMER IEC meeting held on dated 12-04-2022 between 2.00 pm to 4.00 pm at Board room, G Block, Dr. Chandramma Dayanand Sagar Institute of Medical Education and Research (CDSIMER).

The following documents were reviewed:

1. Study Protocol
2. Informed Consent Form with Kannada Language
3. Case Report Form

The following members of the CDSIMER-IEC were present at the meeting

Sl. No	Name	Designation
1	Shri. M N Vidyashankar	Chairperson
2	Dr. Pratibha D Nadig	Member secretary
3	Dr. Meena Nandimath	Basic Medical Scientist
4	Shri. Arvind Moorchung	Legal Expert
5	Dr. S Rajagopalan	Clinician
6	Dr. Yashaswini L S	Clinician
7	Dr. Amita Mukhopadhyay	Clinician
8	Dr. Aravind G N	Clinician
9	Smt. Durga Unnikrishnan	Social Scientist/Ethicist
10	Mr. Sheik Alaudeen M S	Lay Person

The study is **APPROVED** in its revised form.

INSTITUTIONAL ETHICS COMMITTEE

Following points must be noted (whichever is applicable): Date:

1. CDSIMER IEC should be informed of the date commencement of study and submit quarterly progress reports.
2. PI and other investigator should co-operate with CDSIMER IEC, which may monitor study from time to time.
3. New information or any SAE, which could affect this study, must be communicated to CDSIMER IEC and sponsors (If applicable). The PI should report SAEs occurred for CDSIMER IEC approved studies within 24 hrs of the occurrence of the SAE.
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d) If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval.
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f) If there are any amendments in the trial design, these must be incorporated in the protocol and other study document. These revised documents should be submitted for approval of the CDSIMER IEC, only then can they be implemented.
g) Approval for amendment changes must be obtained prior to implementation of changes.
h) The amendment is unlikely to be approved by the CDSIMER IEC unless all the above information is provided.

5. Any deviation/violation/waiver in the protocol must be informed to the CDSIMER IEC.

If project initiation not done in next 1 year from the date of approval from CDSIMER IEC, further extension will not be granted and it will require resubmission to CDSIMER IEC.

Thanks and Regards,

Dr.Pratibha Nadig

Member Secretary

Member Secretary
CDSIMER - IEC
Dr. Chandramma Dayananda Sagar Institute
of Medical Education & Research
Devarakaggalahalli, Kanakapura Taluk, Ramanagara Dt., Karnataka - 562 112

(19/7/22)
Recieved
Anjali

Date:
05.07.2022

Certificate of Approval from CDSIMER-IEC

To

Ms. Anjali Venkat

Principal Investigator,

2nd Year MBBS Student, CDSIMER

Study Ref: CDSIMER/MR/0020/IEC/2022

Dear Ms. Anjali Venkat,

CDSIMER-IEC reviewed and discussed your application received from Internal Scientific Committee to conduct the research study entitled "Assessing magnitude of anaemia using a digital hemoglobinometer: A study amongst women working in a garment factory" during the CDSIMER IEC meeting held on dated 16-06-2022 between 2.00 pm to 4.15 pm at Board room, G Block, Dr. Chandramma Dayanand Sagar Institute of Medical Education and Research (CDSIMER).

The following documents were reviewed:

1. Study Protocol
2. Informed Consent Form with translation in Kannada and Hindi languages

The following members of the CDSIMER-IEC were present at the meeting

Sl. No	Name	Designation
1	Shri. M N Vidyashankar	Chairperson
2	Dr. Pratibha D Nadig	Member secretary
3	Dr. S Rajagopalan	Clinician
4	Dr. Manju Prakash	Clinician
5	Shri. Arvind Moorchung	Legal Expert
6	Dr. Meena Nandimath	Basic Medical Scientist
7	Dr. Yashaswini L S	Clinician
8	Dr. Amita Mukhopadhyay	Clinician
9	Dr. Aravind G N	Clinician
10	Smt. Durga Unnikrishnan	Social Scientist/Ethicist
11	Mr. Sheik Alaudeen M S	Lay Person

The study is **APPROVED** in its presented form.

Date:

Following points must be noted (whichever is applicable):

1. CDSIMER IEC should be informed of the date commencement of study and submit quarterly progress reports.
2. PI and other investigator should co-operate with CDSIMER IEC, which may monitor study from time to time.
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g) Approval for amendment changes must be obtained prior to implementation of changes.
h) The amendment is unlikely to be approved by the CDSIMER IEC unless all the above information is provided.

5. Any deviation/violation/waiver in the protocol must be informed to the CDSIMER IEC.

If project initiation not done in next 1 year from the date of approval from CDSIMER IEC, further extension will not be granted and it will require resubmission to CDSIMER IEC.

Thanks and Regards,

Dr.Pratibha Nadig

Member Secretary

Member Secretary
CDSIMER - IEC
Dr. Chandramma Dayananda Sagar Institute
of Medical Education & Research
Devarakaggalahalli, Harohalli,
Kanakapura Taluk, Ramanagara District - 562112

Date:
05.07.2022

Certificate of Approval from CDSIMER-IEC

To

Mr. Shashank K

Principal Investigator,

2nd Year MBBS Student, CDSIMER

Study Ref: CDSIMER/MR/0021/IEC/2022

Dear Mr. Shashank K,

CDSIMER-IEC reviewed and discussed your application received from Internal Scientific Committee to conduct the research study entitled "A cross sectional study on HbA1C levels and its effect on Visual Memory among offsprings of Diabetics" during the CDSIMER IEC meeting held on dated 16-06-2022 between 2.00 pm to 4.15 pm at Board room, G Block, Dr. Chandramma Dayanand Sagar Institute of Medical Education and Research (CDSIMER).

The following documents were reviewed:

1. Revised Study Protocol
2. Case Report Form

The following members of the CDSIMER-IEC were present at the meeting

Sl. No	Name	Designation
1	Shri. M N Vidyashankar	Chairperson
2	Dr. Pratibha D Nadig	Member secretary
3	Dr. S Rajagopalan	Clinician
4	Dr. Manju Prakash	Clinician
5	Shri. Arvind Moorchung	Legal Expert
6	Dr. Meena Nandimath	Basic Medical Scientist
7	Dr. Yashaswini L S	Clinician
8	Dr. Amita Mukhopadhyay	Clinician
9	Dr. Aravind G N	Clinician
10	Smt. Durga Unnikrishnan	Social Scientist/Ethicist
11	Mr. Sheik Alaudeen M S	Lay Person

The study is APPROVED in its revised form.

Shashank K
Received

Date:

Following points must be noted (whichever is applicable):

1. CDSIMER IEC should be informed of the date commencement of study and submit quarterly progress reports.
2. PI and other investigator should co-operate with CDSIMER IEC, which may monitor study from time to time.
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h) The amendment is unlikely to be approved by the CDSIMER IEC unless all the above information is provided.

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If project initiation not done in next 1 year from the date of approval from CDSIMER IEC, further extension will not be granted and it will require resubmission to CDSIMER IEC.

Thanks and Regards,

Dr.Pratibha Nadig

Member Secretary

Member Secretary
CDSIMER - IEC
Dr. Chandramma Dayananda Sagar Institute
of Medical Education & Research
Devarakaggalahalli, Harohalli,
Kanakapura Taluk, Ra... 562112

Date:
05.07.2022

Certificate of Approval from CDSIMER-IEC

To

Mr. Ratul Chakma

Principal Investigator,

2nd Year MBBS Student, CDSIMER

Study Ref: CDSIMER/MR/0022/IEC/2022

Dear Mr. Ratul Chakma,

CDSIMER-IEC reviewed and discussed your application received from Internal Scientific Committee to conduct the research study entitled "Screening for Cervical Cancer in housekeeping Females by pap smear: A study from a tertiary care Centre in a rural region of Karnataka, India" during the CDSIMER IEC meeting held on dated 16-06-2022 between 2.00 pm to 4.15 pm at Board room, G Block, Dr. Chandramma Dayanand Sagar Institute of Medical Education and Research (CDSIMER).

The following documents were reviewed:

1. Revised Study Protocol
2. Informed Consent Form with translation in Kannada language
3. Questionnaire

The following members of the CDSIMER-IEC were present at the meeting

Sl. No	Name	Designation
1	Shri. M N Vidyashankar	Chairperson
2	Dr. Pratibha D Nadig	Member secretary
3	Dr. S Rajagopalan	Clinician
4	Dr. Manju Prakash	Clinician
5	Shri. Arvind Moorchung	Legal Expert
6	Dr. Meena Nandimath	Basic Medical Scientist
7	Dr. Yashaswini L S	Clinician
8	Dr. Amita Mukhopadhyay	Clinician
9	Dr. Aravind G N	Clinician
10	Smt. Durga Unnikrishnan	Social Scientist/Ethicist
11	Mr. Sheik Alaudeen M S	Lay Person

The study is **APPROVED** in its revised form.

Date:

Following points must be noted (whichever is applicable)

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2. PI and other investigator should co-operate with CDSIMER IEC, which may monitor study from time to time.
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g) Approval for amendment changes must be obtained prior to implementation of changes.
h) The amendment is unlikely to be approved by the CDSIMER IEC unless all the above information is provided.

5. Any deviation/violation/waiver in the protocol must be informed to the CDSIMER IEC.

If project initiation not done in next 1 year from the date of approval from CDSIMER IEC, further extension will not be granted and it will require resubmission to CDSIMER IEC.

Thanks and Regards,

Dr.Pratibha Nadig

Member Secretary

Member Secretary
CDSIMER - IEC
Dr. Chandramma Dayananda Sagar Institute
of Medical Education & Research
Devarakaggalahalli, Harohalli
Kanakapura Taluk, Ra... ...112

CDSIMER
Dr. Chandramma Dayananda Sagar
Institute of Medical Education and Research
(Unit of Dayananda Sagar University)

INSTITUTIONAL ETHICS COMMITTEE

(Regn. ECR/1628/Inst/KA/2021)

Date:
05.07.2022

Certificate of Approval from CDSIMER-IEC

To

Mr. Ratul Chakma

Principal Investigator,

2nd Year MBBS Student, CDSIMER

Study Ref: CDSIMER/MR/0022/IEC/2022

Dear Mr. Ratul Chakma,

CDSIMER-IEC reviewed and discussed your application received from Internal Scientific Committee to conduct the research study entitled "Screening for Cervical Cancer in housekeeping Females by pap smear: A study from a tertiary care Centre in a rural region of Karnataka, India" under the guide Dr.Archana Shetty,Professor Pathology,CDSIMER during the CDSIMER IEC meeting held on dated 16-06-2022 between 2.00 pm to 4.15 pm at Board room, G Block, Dr. Chandramma Dayanand Sagar Institute of Medical Education and Research (CDSIMER).

The following documents were reviewed:

1. Revised Study Protocol
2. Informed Consent Form with translation in Kannada language
3. Questionnaire

The following members of the CDSIMER-IEC were present at the meeting

Sl. No	Name	Designation
1	Shri. M N Vidyashankar	Chairperson
2	Dr. Pratibha D Nadig	Member secretary
3	Dr. S Rajagopalan	Clinician
4	Dr. Manju Prakash	Clinician
5	Shri. Arvind Moorchung	Legal Expert
6	Dr. Meena Nandimath	Basic Medical Scientist
7	Dr. Yashaswini L S	Clinician
8	Dr. Amita Mukhopadhyay	Clinician
9	Dr. Aravind G N	Clinician
10	Smt. Durga Unnikrishnan	Social Scientist/Ethicist
11	Mr. Sheik Alaudeen M S	Lay Person

The study is **APPROVED** in its revised form.

Address
Devarakaggalahalli, Kanakapura Road,
Ramanagara Dt, Karnataka - 562 112

Phone
+91 80 2608 6500

E-mail
iec.cdsimer@dsu.edu.in

Website
www.cdsimer.edu.in

Following points must be noted (whichever is applicable):

Date: 05/07/2022

1. CDSIMER IEC should be informed of the date commencement of study and submit quarterly progress reports.
2. PI and other investigator should co-operate with CDSIMER IEC, which may monitor study from time to time.
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Thanks and Regards,

Dr.Pratibha Nadig

Member Secretary

Member Secretary
CDSIMER - IEC
Dr. Chandramma Dayananda Sagar Institute
of Medical Education & Research
Devarakaggalahalli, Harohalli,

Received
RATUL CHAKMA
16/09/22

Certificate of Approval from CDSIMER-IEC

Date:

To

Ms. Shreya Rajiv Bijjal

Principal Investigator,

2nd year MBBS Student, CDSIMER

Study Ref: CDSIMER/MR/0033/IEC/2022

Dear Ms. Shreya Rajiv Bijjal,

CDSIMER-IEC reviewed and discussed your application received from Internal Scientific Committee to conduct the research study entitled "Pattern of change in weight in normal term breastfed babies in cross cradle technique in normal delivery and Caesarean delivery from birth to six weeks in a new rural university medical college hospital" during the CDSIMER IEC meeting held on dated 09-08-2022 between 2.00 pm to 4.00 pm at Board room, G Block, Dr. Chandramma Dayanand Sagar Institute of Medical Education and Research (CDSIMER).
The following documents were reviewed:

1. Study Protocol
2. Informed Consent Form with translation in Kannada language
3. Case Report Form

The following members of the CDSIMER-IEC were present at the meeting

Sl. No	Name	Designation
1	Shri. M N Vidyashankar	Chairperson
2	Shri. Arvind Moorchung	Legal Expert
3	Dr. Meena Nandimath	Basic Medical Scientist
4	Dr. Yashaswini L S	Clinician
5	Dr. Amita Mukhopadhyay	Clinician
6	Dr. Aravind G N	Clinician
7	Smt. Durga Unnikrishnan	Social Scientist/Ethicist
8	Mr. Sheik Alaudeen M S	Lay Person
9	Dr. Pratibha D Nadig	Member secretary

The study is **APPROVED** in its presented form.

Received
Bijjal
19/8/2022

Date: 17.08.2022

Following points must be noted (whichever is applicable):

1. CDSIMER IEC should be informed of the date commencement of study and submit quarterly progress reports.
2. PI and other investigator should co-operate with CDSIMER IEC, which may monitor study from time to time.
3. New information or any SAE, which could affect this study, must be communicated to CDSIMER IEC and sponsors (If applicable). The PI should report SAEs occurred for CDSIMER IEC approved studies within 24 hrs of the occurrence of the SAE.
4. In the event of any protocol amendments, CDSIMER IEC must be informed and the amendments should be highlighted in clear terms as follows:

a) The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project (Page No., Clause No. etc.)
b) The PI must comment how proposed amendment will affect the ongoing study
c) Alteration in the budgetary status, staff requirement should be clearly indicated and the revised budget form should be submitted.
d) If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval.
e) If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
f) If there are any amendments in the trial design, these must be incorporated in the protocol and other study document. These revised documents should be submitted for approval of the CDSIMER IEC, only then can they be implemented.
g) Approval for amendment changes must be obtained prior to implementation of changes.
h) The amendment is unlikely to be approved by the CDSIMER IEC unless all the above information is provided.

5. Any deviation/violation/waiver in the protocol must be informed to the CDSIMER IEC.

If project initiation not done in next 1 year from the date of approval from CDSIMER IEC, further extension will not be granted and it will require resubmission to CDSIMER IEC.

Thanks and Regards,

Dr. Pratibha Nadig
Member Secretary

Member Secretary
CDSIMER - IEC
Dr. Chandramma Dayananda Sagar Institute
of Medical Education & Research
Dr. Anekal Taluk, Harohalli,
Kanakapura Road, Ramanagara District - 562112

NAPTICON 2022

First Annual National Conference of National Association of Pharmacology & Therapeutics

Organized by: Department of Pharmacology, Father Muller Medical College, Mangaluru.

Date: 28th and 29th October 2022 | Venue: Father Muller Convention Center, Mangaluru.

CERTIFICATE OF PARTICIPATION

presented to

VISHAL KR

for presenting an e-Poster Presentation on the topic

PARACETAMOL SELF-OVERDOSING CASE SERIES STUDY- ANALYSIS OF DEMOGRAPHY, CLINICAL FEATURES AND TREATMENT METHODS

during the scientific session of **NAPTICON - 2022**

held on **28th and 29th October 2022** at **Father Muller Convention Center, Mangaluru, Karnataka.**

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Original Research Article

Paracetamol Self Overdosing Case Series Study- Analysis of Demography, Clinical Features and Treatment Methods

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Conflict of interest: Nil

Abstract

Background: Acute liver failure due to Paracetamol overdosing is the second most common cause requiring liver transplantation worldwide.

Objectives: To analyze the demographic features, clinical features and treatment methods used in Paracetamol self-overdosed patients at a tertiary care center in South India.

Methods and Material: A retrospective case series study was conducted after obtaining Ethics Committee approval. Patients reported with Paracetamol overdosing with or without additional drugs from 01 Jan 2020 to 31 Dec 2021 were included in the study. Data collection form was used to collect data on demography, clinical presentation, past/medication/personal history, general physical, vitals, and systemic examination. In addition Psychological evaluation and Treatment methods were also collected. Descriptive statistics applied. Demography, clinical features and treatment methods were analyzed using Instat3 and Microsoft Excel.

Results: Thirteen patients aged 26.15±12.35 years who consumed 10±5.195 tablets amounting to 6.23±3.23 grams of Paracetamol as a single dose were analyzed. Vomiting and pain abdomen were common presenting complaints. Signs of injury to GIT and CNS organs were noted in these patients. Seven patients were discharged against the medical advice. All patients received gastric lavage and other supportive treatments as early as possible at a nearby government hospital or at our centre.

Conclusions: Young female patients, easy availability of OTC medicines and conflict with family members were the three important factors which contributed to intentional Paracetamol overdosing in our study. We recommend CDSCO, India to take cognizance of amendments made by FDAs of UK and USA with regard to Paracetamol product label and consider similar actions to prevent loss of lives due to Paracetamol overdosing.

Keywords: Paracetamol Overdosing, Demography, Clinical features, Treatment

Introduction

Paracetamol (acetaminophen) was discovered by Harmon Northrop Morse in 1878. It is the most frequently purchased over-the-counter (OTC) medicine even 140 years after its invention. Paracetamol alone or its fixed dose combinations (FDCs) with other non-steroidal anti-inflammatory drugs (NSAIDs) are the most widely used analgesic and antipyretic agents in the world [1-3]. Paracetamol is a cheaper, yet effective analgesic and antipyretic agent. It is issued to patient without doctor's prescription due to its OTC status in the market. Many patients are abusing this opportunity to commit suicide by intentional overdosing [2].

In USA alone, more than 56,000 patients visit to emergency department due to Paracetamol overdosing. Among these, 2600 are hospitalized and 500 die every year. Acute liver failure (ALF) is the major cause of mortality in these patients. ALFs due to intentional or unintentional Paracetamol overdosing is the second most common cause requiring liver transplantation worldwide [4].

Several preventive steps have been initiated by western Food and Drug regulatory agencies with the intention to prevent self-overdosing of Paracetamol. UK regulatory agency issued notifications to limit the OTC Paracetamol sale to maximum 8 grams per person and insisted for blister packaging. USFDA limited the dose of Paracetamol in FDCs to 325 mg per tablet and ordered to change the product label to include black-box warning. As a result of this, patients getting admitted to liver clinical units were reduced and liver transplants due to Paracetamol induced ALFs were also reduced [5].

Marzilawati *et al*. conducted a four year clinical observational study on 1024 patients with Paracetamol overdosing and reported that 33.2% of them belonged to Indian origin [6]. Another 10 year retrospective hospital based study reported 0.32% cases of acute Paracetamol overdosing due to accidental exposures [3]. Compared to western countries, minimal data is available on Paracetamol self-overdosing in Indian population. Therefore, we conducted this case series study with the objective to analyze the demographic features, clinical features and treatment methods used in Paracetamol self-overdosed patients who reported to our tertiary care centre.

Materials and Methods

This is a retrospective case series study initiated at a tertiary care center in South India after obtaining Ethics Committee approval (ref no. CDSIMER/MR/0008/IEC/2022). Waiver for consent procedure was also obtained at the time of Ethics Committee approval.

Inclusion criteria:

- All the patients with self-Paracetamol overdosing with or without additional drugs.
- Patients treated at emergency department either as in-patient or out-patient basis.
- Patients reported to our tertiary care center during study period i.e., from 01 Jan 2020 to 31 Dec 2021.

Exclusion criteria:

- Patients with history of overdosing/poisoning without Paracetamol as one of the chemical ingredient.

Data collection: Customized data collection form (DCF) was designed and same was used for data collection. Permission of administrators and medical records section incharge was taken before accessing the data. Case sheets were reviewed and data extracted into DCF on factors related to demography, clinical presentation, history of present illness, past history, medication history and personal history. Findings of general physical examination, vitals monitoring, systemic

examination, Glasgow coma scale assessment, Psychological evaluation and Treatment methods were also collected. Strict confidentiality was maintained and patient identifiers were masked.

Statistical analysis: Data from DCFs were computerized and tabulated using Microsoft excel software. The data was further processed using descriptive statistics. Mean, standard deviation (SD), Median, Minimum and Maximum values were calculated using Instat 3 statistical software. All the remaining data were presented using tables.

Results

Total 13 patients reported with the history of Paracetamol self-overdosing during the study period. Higher number of female (N=10) patients attempted suicide when compared to male (N=3). Second half of the day (afternoon and evening) was the preferred time to attempt suicide. On an average 10±5.195 (mean±SD) tablets equivalent to 6.23±3.23 grams of Paracetamol was consumed by these patients. Majority of the patients were transferred to local government hospital or to our tertiary care centre within one to five hours after consumption of the drug/s. Six patients accepted to stay in the hospital for proper evaluation and treatment. Remaining seven patients ignored the advice of the doctors and demanded for discharge against medical advice (DAMA). Table No. 1 provides details of patient's demography, time and amount of consumption, time of reporting and duration of hospital stay following Paracetamol overdosing.

Table 1: Patient's demography, time and amount of consumption, time of reporting and duration of hospital stay following Paracetamol overdosing.

S. N.	Parameter	N	Mean	SD	Median	Minimum	Maximum	Comment (N)
1	Age	13	26.15	12.35	21	7	55	Male (3), and Female (10)
2	Time of consumption of the day	13	15.53	4.375	17.5	9	24	Morning (2), Afternoon (4) Evening (5) patients, Night (2) Place of Suicide attempted: home (12), farm (1).
3	Number of Paracetamol Tablets consumed	12	10.41	5.195	9	5	20	Handful of tablets consumed (1). So, not able to identify the number of tablets. Strength of Tablets: 325 mg (1), 500 mg (2), 650 mg (10).
4	Amount of Paracetamol consumed in grams	12	6.23	3.23	5.85	2.6	13	Not able to estimate (1)
5	Time of reporting to hospital	13	15.24	5.705	16.5	1.95	22	Time in 24 Hour format.
6	Time delay in reporting after consumption	13	4.32	6.1	2.5	0.58	24	All reported within 5 hours after consuming Paracetamol (except one patient who reported after 24 hours as he was treated at another hospital till that time)
7	Average hospital stay - Normal discharge	6	2.83	2.137	2	1	7	*DAMA (7); OPD patients (4), In-patients (3). Among admitted, two days (2), one day (1)
*DAMA - Discharged early against medical advice								

Overdosing of Paracetamol alone was observed in 5/13 patients. Remaining 8/13 patients consumed one or more additional drugs along with Paracetamol. Details of these drugs are given in Table No. 2.

Table 2: Details of concomitantly consumed drugs along with Paracetamol overdosing

Sl. No.	N	Details*
1	5	Consumed Paracetamol alone
2	8	Consumed other drugs along with Paracetamol
	1	2 Multivitamin tablets
	1	3 Azithromycin tablets, 2 FDC of Montelukast + Cetirizine tablets, 4 Pantoprazole capsules
	1	10 Folic acid tablets
	1	8 Nimesulide
	1	90-180 ml of Alcohol
	1	8 Zinc Sulphate tablet
	1	5 Cephalexin tablets
	1	75 ml of syrup. Drug name not identified
*Strengths of each unit/s were not identified by patient while giving history. Therefore, only number of units is mentioned.		

After receiving the patients at our hospital, brief presenting complaints and other clinical histories were recorded. Same was analysed and results are tabulated in Table No. 3. Vomiting and pain abdomen were the common presenting complaints. Ten (10/13) patients did not have any significant past history but 3/13 patients had significant past history; first patient had depression due to her son's alcohol consumption; second patient had hallucinations and other psychosis related symptoms and was treated by a traditional healer; third patient had depression due to hyperemesis gravidarum and conflict with her brother-in-law. See Table No. 03 for other details.

Table 3: Clinical features based on presenting and past history of Paracetamol overdosed patients

S. N.	Parameter	Patients with No Significant Events (N)	Patients with Significant Events (N)	Description of events (N)
1	Symptoms	4	9	Vomiting (8), Pain abdomen (3), Loss of consciousness (2), Nausea (1), Self-fall with head injury and extremities injury (1), Three months amenorrhea (1)
2	Past history	10	3	Hyperemesis gravidarum (1), Depression (1), On psychotropic drugs as a treatment for possession and irrelevant talk (1)
3	Diet	13	0	All patients were having mixed diet (13)
4	Habits	11	2	Occasional alcohol consumption (2)
5	Appetite	12	1	Reduced (1)
6	Sleep	11	2	Reduced since 15 days (2)
7	Drug allergy	13	0	No drug allergy (13)
8	Past medication intake	12	1	Past psychotropic drug use (1)
9	Previous investigations results	13	0	None available (13)
10	Patient treated at other hospitals before reaching tertiary care center	6	7	Patients reached directly tertiary centre (7), Treated at local PHC before reaching tertiary centre (6); Gastric lavage done (6), NAC treatment done (1)

All patients were found to have well-built and well-nourished body without any nutritional deficiencies. Majority of patients had stable vital parameters except: 3/13 had tachycardia; 2/13 had tachypnea, 1/13 had hypertension (freshly detected, not on any medication).

All patients had normal body temperature, peripheral capillary oxygen saturation (SPO2), random blood glucose (RBS), cardiovascular (CVS), respiratory systems (RS), Gastrointestinal tract (GIT) and Central nervous system (CNS) except: 1/13 had tenderness of right hypochondriac region; 1/13 had tenderness at sacral and right iliac region; 1/13 had drowsiness and responded on verbal stimulation; 1/13 had impaired judgment. Other details are tabulated in Table No. 4.

Table 4: Vitals and Systemic examination Results of Paracetamol overdosed patients

Sl. No.	Type of examination and description of results							
I	Vitals Examination							
	Parameter	**N**	**Mean**	**SD**	**Median**	**Minimum**	**Maximum**	**Comment (Normal Reference Range)**
1	Body temperature	13	97.85	0.624	98	96.8	98.6	All 13 patients had normal body temperature (97.7 to 99.5 degrees Fahrenheit {36.5 to 37.5 degrees centigrade} [7])
2	Pulse	13	86.15	13.195	82	70	110	Three patients had Tachycardia. Ten patients had Normal pulse. (60-100 beats/min [7])
3	Respiratory rate	13	20.23	3.21	20	16	26	Three patients had Tachypnea. Ten patients had Normal respiratory rate (12-20/min [7])
4	SPO2	13	98.23	1.536	98	95	100	One patient had 95% SPO2. 12 patients had Normal SPO2 (96% or higher) [8]
5	Systolic blood pressure	13	120.46	20.019	120	96	170	Four patients had Higher Systolic BP (>120 mm of Hg[7]). Nine patients had Normal systolic BP (<120 mm of Hg [7])
6	Diastolic blood pressure	13	74	11.94	78	54	100	One patient had above normal Diastolic BP (>80 mm of Hg[7]). 12 patients had Normal diastolic BP (50-80 mm of Hg [7])
7	Random blood glucose (RBS)	8	108	19.01	103	84	136	Three had higher RBS. Five Patients had normal RBS. (72 to 108 mg/Dl[9]). In five patient's RBS not tested.
II	Systemic Examination (N)							
1	General physical examination	No pallor (13), No Cyanosis (13), No clubbing (13), No icterus (13), No lymphadenopathy (13), No Peripheral oedema (12), Extremities oedema due to local injury (1)						

2	Systemic examination	No CVS abnormality (13)
		No Respiratory system abnormality (13)
		No per abdominal abnormality (11), Tenderness of right hypochondriac region (1), Tenderness at sacral and right iliac region (1),
		No CNS abnormality (11), Drowsiness and arousal on verbal stimulation (1), Judgment impaired (1)
3	Glasgow Coma Scale Assessment	15/15 score (6), 14/15 score (5), 13/15 score (2), Verbal - Disoriented (6), Eye opening - to call (1), Motor - abnormal flexion (1)

All the patients were suggested to follow standard treatment guidelines. Six (6/13) patients agreed to follow the patient management strategy. Remaining 7/13 patients requested for discharge against the medical advice (DAMA) after receiving part of treatment. Twelve (12/13) patients received gastric lavage, intravenous fluids, proton pump inhibitors (PPIs), and anti-emetics. One patient reported late (after 24 hrs.) after overdosing. He was treated in another hospital. His treatment details were not available. Four patients were treated with specific antidote N-Acetyl-Cysteine (NAC). Other details are summarized in Table No. 5.

Table 5: Summary of treatment methods used for Paracetamol overdosed patients

Sl No	Method of Treatment	N		Comments (N)
		Received	Not received	
1	Gastric Lavage	12	1	Self-induced vomiting (1), With charcoal (1), Without charcoal (10)
2	N acetyl cysteine	4	9	Complete course given over 21 hours as per standard therapeutic guidelines.
3	Intravenous fluid	12	1	Dextrose normal saline (12), Ringer lactate (12), Dextrose IV fluids (12) as per Standard therapeutic guidelines
4	Restriction of Oral food/Fluid	8	5	Ryle's tube inserted (8)
5	Antibiotics	3	10	Ceftriaxone given (3)
6	Multivitamins and nutrients	5	8	Vitamin B complex (4), Oral Iron supplement (1), Lactic Acid Bacillus (1), Glutathione (1)
7	Proton Pump Inhibitors	12	1	Pantoprazole (12)
8	Anti-emetics	12	1	Ondansetron (12)
9	Oral Antacids	1	12	Antacid fixed dose combination (FDC) syrup containing Oxethazaine (10 mg/5ml), Aluminum Hydroxide (0.291 gm/5ml), and Milk of Magnesia (98mg/5ml) (1)
10	Hepato-protective agents	1	12	FDC containing Lecithin, Silymarin, Glutathione, Zinc, Amino acids, Vitamins (1)
11	Drugs acting on CNS	3	10	Escitalopram (1), Paroxetine (1), Clonazepam (2), Mirtazapine (1)
12	Anti-spasmodic agents	1	12	Drotaverine (1)
13	Psychological assessment and Psychotherapy	5	8*	Conflict present (4), No conflict (1)
				a. Alcoholic businessman; incurred loss; argued with parents; parents scolded the son.(1)
				b. Difference of opinion between parents and daughter (1)
				c. Recently married lady; Suspicion of possession; Hallucinations; Illusions; Psychosis; External voice provoked and guided to consume tablets; No suicidal intentions. (1)

				d. Depressed mother; Younger son started consumption of alcohol (1)
				e. Pregnant women and hyperemesis; Depression; Conflict with brother-in-law; Bad language; Confrontation. (1)
				*patients were not available for psychiatrist's consultation as they were discharged on DAMA basis. One patient discharged before psychiatrist's consultation as hospital stay was short.

In addition to above therapeutic agents, five patients were evaluated by psychiatrists and psychotherapy with counselling was given to these patients. Observations of psychiatrists are given in the Table No. 5.

Discussion

Development of suicidal thoughts is the result of complex interactions of biological, genetic, psychological, sociological and environmental factors [10]. The World Health Organization (WHO) has updated in its website that more than 700,000 people die due to suicide and it is the fourth leading cause among 15-19 year-olds [11]. In India alone, more than 1,00,000 people commit suicide every year. This increased to 1,39,123 suicides in the year 2019. Suicides in the third decade of life (i.e., in persons of 20 to 29 years age) accounts for 41 to 62% of all suicides. In our study, the mean±SD age of patients was 26.15±12.35 yrs (with median age 21 yrs) which is in concordance with WHO and Anil R et. al., reports [10].

According to Anil R et. al., worldwide general suicidal tendency is not gender specific and varies from report to report [10]. In our study, 10/13 were female patients. This may be a special characteristic of Paracetamol poisoning. Our findings is again supported by Narongchai P et.al., study where 16 of 21 patients (76%) were female patients [12]. CL Sheen *et al*., also mentioned that intentional overdose was seen frequently in teenagers, the majority of whom were female patients [13].

In our study, majority of patients attempted suicide in the second half of the day and reported to our hospital after the working hours to emergency department consuming 5-20 tablets (average 12±10.41 tablets). Commonly consumed strength of each tablet was 650 mg and average total dose was 6.23±3.23 grams. These readings were relatively less than those reported by Narongchai P et.al [12].

According to Narongchai P et.al., the motivation for Paracetamol overdosing was quarrelling with a boy or girl friend [12]. We agree with their findings. In our study also it was found that majority of the patients who were evaluated by psychiatrist confirmed the presence of conflict with one or the other family members. A minor who got overdosed was due to accidental consumption and no conflict was identified. Another person who got recently married had signs and symptoms of psychosis and was treated by local faith healer for possession and hallucinations.

Patients were not evaluated for classical signs and symptoms of stages of Paracetamol poisoning as majority of the patients did not stay in the hospital for more than 2 days. Seven patients were discharged on DAMA basis on the same day or next day of admission. Major presenting complaints were vomiting, pain abdomen, loss of consciousness and nausea. These signs/symptoms were in line with stage 1 and 2 of Paracetamol poisoning [4].

Majority of patients reached nearby government hospital or our tertiary care center and received appropriate treatment

including gastric lavage, Ryle's tube insertion (nil orally), intravenous fluids and multivitamins etc. The average time to reach our tertiary care center was 4.32±6.1 hours. But 7/13 patients were subjected to gastric lavage at the government hospital before reaching our center. Remaining 6/13 patients received gastric lavage at our hospital (one patient induced vomiting herself immediately after drug consumption). Among those who reached directly to our hospital, reported as early as 0.58 hrs (average 1.62 hours) after self-overdosing. Almost all patients (12/13) received proton pump inhibitor (pantoprazole) and antiemetic ondensetron. Four (4/13) patients received NAC and remaining were not willing to undergo treatment as per physicians suggestions and requested for DAMA.

As per Zapatero D C et.al., on comparing Paracetamol overdosing due to single dose Vs multiple doses, former was found to have better outcome. Those patients who report early could be managed successfully in the emergency department itself [14]. All patients in our study, had single dose of Paracetamol and had gastric lavage as early as possible. This might have helped them to recover faster and could overcome the deleterious effects of Paracetamol overdosing.

As reported by Schmidt L E *et al*., concomitantly overdosed drugs may affect the patient outcome through independent toxic or hepato-protective properties or through pharmacokinetic interaction with Paracetamol [15]. In our study, 8/13 patients had following concomitant drugs along with Paracetamol overdosing: Vitamins and other nutritional supplements; anti-histaminic drugs; proton pump inhibitors; antibiotics and other NSAIDs. Based on this, concomitantly administered drugs need not be always toxic to patients.

General physical examination, vitals, systemic examination findings were normal in majority of patients except few patients who had signs like: tenderness of right hypochondriac region; tenderness at sacral and right iliac region; impairment of judgment and drowsiness. These signs and symptoms were suggestive of injury to GIT and CNS organs.

As reported by other workers, almost all the victims of Paracetamol overdosing survive with or without chemical induced organ damage [12]. In our study, even though some patients got discharged against medical advice after initial treatment, all patients were stable and uneventfully discharged. Therefore we agree with findings of Narongchai P et.al.

In another report Agrawal S et.al., mentioned that mortality can be as low as 2% if the patients are diagnosed and treated promptly. As less as 1-3% of patients may die due to severe liver failure and may need liver transplant for survival [4]. Gulmez S E *et al*., reported that Paracetamol overdose was found to represent one-sixth of all causes ALFT (acute liver injury leading to registration on transplantation lists). Among drug overdose patients who registered in the liver transplantation lists, Paracetamol overdosing is considered as the causative agent in 97.3% of the cases [16].

Paracetamol at therapeutic (adults doses at 650 mg to 1000 mg every 4 to 6 hours, not exceeding 4 grams/day and children doses at 15 mg/kg every 6 hours, up to 60 mg/kg/day) doses has a good safety profile. Toxic doses (7.5 g/day to 10 g/day or 140 mg/kg) can cause severe liver injury[4]. In our study, 3/13 patients consumed more than 7.5 g of Paracetamol as a single dose. All of them were subjected to decontamination within 2 hours after consumption. No fatal outcomes were recorded.

Schmidt L E *et al*., reported that the choice of method to commit suicide reflect on easy availability of the drugs, popularity of the drug, national and regional prescribing practices, etc [15]. According to current status, in India, Paracetamol is an OTC medication and patients are able to purchase without restriction on number of units and total amount of drug in grams. We agree with Schmidt L E et. al., on the reasons proposed for considering Paracetamol as the agent for committing suicide. Various regulatory agencies have implemented several preventive steps to reduce self-poisoning using Paracetamol. UK regulatory agency limited the OTC Paracetamol sale to maximum 8 grams per person and insisted for blister packaging (instead of bottles) of its products. USFDA limited the dose of Paracetamol in prescription FDCs with other NSAIDs to maximum 325 mg per tablet and recommended to include black-box warnings on these products. As reported by Bari K *et al*, these measures lead to reduction in overdose cases admissions to liver units and number of liver transplants due to Paracetamol overdosing[5]. We recommend to implement similar measures by CDSCO (Central Drugs Standards Control Organization, India) to prevent vital organs injury and related complications of Paracetamol overdosing. We also recommend to conduct additional studies to collect additional evidences to establish baseline characteristics of Indian population. Same may be used for monitoring the results of the altered regulations.

Limitations: This case series study can only act as a pilot study due to its limited sample size. Therefore, the observations made in this study need further confirmation through additional studies with larger sample size. We recommend to conduct additional studies with larger sample size to establish the baseline characteristics that are specific to Indian population. The data thus generated may help to substantiate the regulatory actions that may be recommended by the expert panel at CDSCO. Laboratory parameters and other investigations data were not discussed in this article due to restrictions in words and number of tables per research paper. The remaining data will be presented in a separate research paper.

Conclusion

To conclude, young female patients were more prone to intentional Paracetamol overdosing due to easy availability through unlimited OTC purchase (without needing prescription). Psychological evaluation confirmed the presence of conflict with family members as the major promoting factor for suicidal attempt. Less frequent causes were unintentional accidental consumption and psychosis (possession).

Majority of patients retained normal vitals and systemic organ functions. GIT and CNS were frequently affected organs and were presented with signs and symptoms like nausea, vomiting, pain abdomen, drowsiness, loss of orientation and unconsciousness, but responded on verbal stimulation. Majority of patients reported to nearby hospital for emergency management and they were administered treatment as per standard treatment guidelines. The treatment included gastric lavage, Ryle's tube insertion (nil orally), intravenous fluids, use of drugs like proton pump inhibitors, antiemetics and multivitamins. Good number of patients requested for DAMA. Remaining patients who were treated as inpatient and were administered with additional drugs like NAC, hepatoprotective agents, antipsychotics, antidepressants, anxiolytics, antibiotics, oral antacids and antispasmodics. All patients survived and no fatal outcome recorded.

Acute Liver Injury due to Paracetamol overdosing tops the ALFT due to drug overdosing. As a preventive measure, USA and UK regulatory agencies have taken

actions and restricted the total amount of Paracetamol that can be issued to general public on OTC basis and mandated label changes to include black-box warning. Change in Packaging was ordered and mandated to have blister packing. We recommend CDSCO to take cognizance of such changes in regulations and amend the existing rules to avoid loss of lives due to Paracetamol overdosing and need for liver transplantation. In addition, we recommend to conduct further studies to establish Indian specific baseline clinical data on Paracetamol overdosing to verify the results of actions taken and strengthen the evidences for better measures in future.

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